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The Journal of the Connecticut State Medical Society

VOLUME 43 [redacted] 1979 [redacted]

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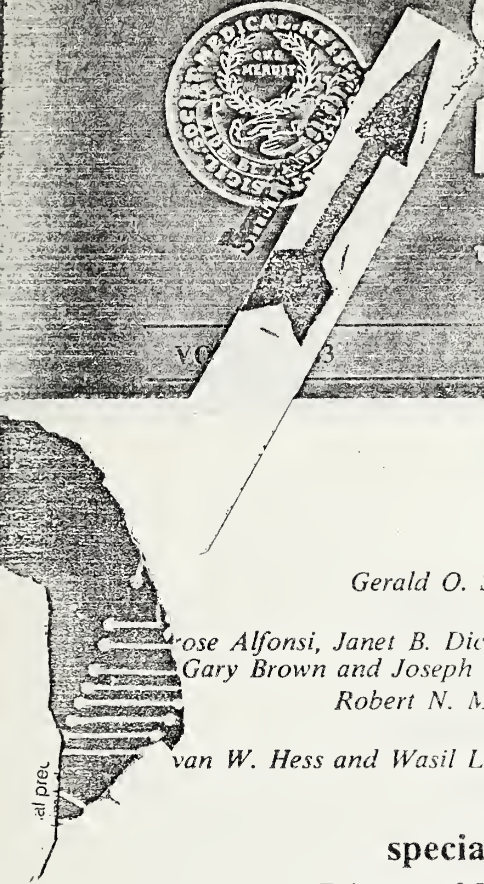

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# Categorization of Hospital Emergency Service Capabilities: The Connecticut Model

GERALD O. STRAUCH, M.D.

Categorization of hospital emergency service capabilities in Connecticut has been a complex process. Although it has been accomplished by health professionals, the undercurrents of politics and economics have been ever present and near the surface of all of our deliberations.

What I would like to do is to describe the historical underpinnings and the process of categorization peculiar to Connecticut and then to attempt to evaluate the process and its significance, as I see it, to date and for the future.

The same national thrusts that generated the development of emergency medical services (EMS) in so many areas of the country in the late 1960's resulted in the Yale Trauma Program in Connecticut. The program was initially co-directed by Alfred M. Sadler, Jr., M.D. and Blair L. Sadler, J.D. (They are twins.) The Sadlers immediately focused on EMS development as the central theme of the Yale Trauma Program. Among the main issues to be addressed was the status of hospital emergency departments in Connecticut, and early in 1975, under the auspices of the Connecticut Committee on Trauma of the American College of Surgeons and the Connecticut State Medical Society, the Department of Epidemiology and Public Health of the Yale University School of Medicine, with Samuel B. Webb, Jr., Dr. P.H., as the mastermind and Eileen M. O'Gara as author, gave Connecticut its first statewide look at its hospital emergency services.[1]

Meanwhile, a statewide ad hoc committee, the Connecticut Advisory Committee on Emergency Medical Services, organized in late 1970, had begun the process of encouraging EMS legislation for the state. In 1974 the Connecticut Emergency Medical Services Act was passed by the state legislature.[2]

Categorization of hospital emergency services capabilities was mandated by the new law, but no mechanism for developing categorization had been specified. Having become Chairman of the Connecticut Committee on Trauma of the American College of Surgeons in 1974, I was approached by Thomas Brask, the new Director of the Connecticut Office of Emergency Medical Services under the EMS Act, regarding categorization. I volunteered the services of my committee to begin the categorization task early in 1975.

Shortly thereafter, I asked nine people to participate with me in the initial categorization effort. All ten of us had longstanding interest in Connecticut's EMS effort, and all were medical or public health professionals. Many had multiple credentials and organizational responsibilities which I hoped would lend real stature and authoritative credibility to the group. We became the Task Force on Categorization of Hospital Emergency Services.

Organizations with which Task Force members were associated included:

1. American Association for the Surgery of Trauma
2. American Burn Association
3. American College of Emergency Physicians
4. American Trauma Society
5. Committee on Trauma, American College of Surgeons
6. Connecticut Advisory Committee on Emergency Medical Services

---

GERALD O. STRAUCH, M.D., Vice-Chairman, Connecticut Advisory Committee on Emergency Medical Services; Chairman, Task Force on Categorization of Hospital Emergency Services; Chairman, Task Force on Care Capability and Chairman, Connecticut Committee on Trauma, American College of Surgeons.

*From an Address to the Invitational Conference on the Categorization of Hospital Emergency Capabilities, Sponsored by the American Medical Association and the American Hospital Association, July 19-21, 1978, Chicago, IL.*

*Reprint Requests to: 70 Mill River Street, Stamford, CT 06902 (Dr. Strauch).*

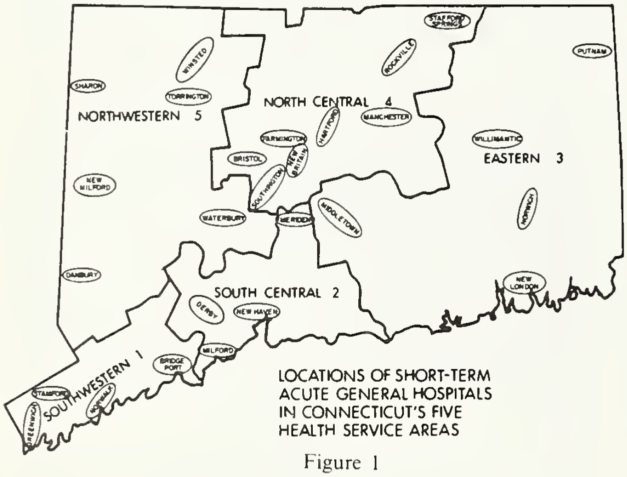
7. Connecticut Hospital Association
8. Connecticut Society of American Board Surgeons
9. Connecticut State Medical Society
10. Emergency Department Nurses Association
11. Yale Trauma Program

The first decision made by the Task Force was to base the categorization on inventory criteria. While we recognized that performance is the bottom line in delivery of medical care, it was apparent that measuring performance at our stage of the categorization endeavor was unrealistic and that we would be talking in terms that had no history in categorization. Performance criteria would have to come later.

We obtained the inventory criteria used by other organizations and states. After studying a number of them, we decided to devise our own criteria and to divide criteria into two major divisions: 1) those pertaining to the hospital's emergency department and 2) those pertaining to the hospital in which the emergency department was located. Further, it seemed appropriate to limit this initial phase of categorization to Connecticut's 35 short-term acute general hospitals, (Figures 1, 2) which care for such a large percentage of the total number of persons with emergency medical problems in the state.

The general aspects of hospital and hospital emergency department characteristics we considered are listed in Table 1. For those who wish to study the criteria in detail, they were published in 1977 in the book by the Sadler brothers and Sam Webb, entitled *Emergency Medical Care: The Neglected Public Service.*[3]

The Task Force decided that Connecticut should have a standard for hospital emergency services; consequently, a three-tiered categorization scheme emerged. The three categories or levels of hospitals were to be characterized as offering standard, major, or comprehensive emergency services. In brief, the three hospital categories were defined as follows: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BRISTOL
NEW BRITAIN
SOUTHINGTON
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MIDDLETOWN
NORWICH
DANBURY
NEW LONDON
SOUTH CENTRAL 2
DERBY
NEW HAVEN
MILFORD
BRIDGE PORT
SOUTHWESTERN 1
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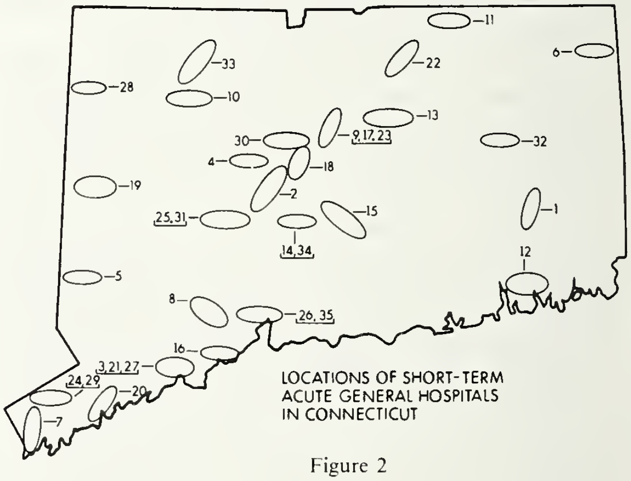
NORWALK
GREENWICH

LOCATIONS OF SHORT-TERM ACUTE GENERAL HOSPITALS IN CONNECTICUT'S FIVE HEALTH SERVICE AREAS

Figure 1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16
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7

LOCATIONS OF SHORT-TERM ACUTE GENERAL HOSPITALS IN CONNECTICUT

Figure 2

| *Hospitals* | *Number* |
|---|---|
| Backus, Norwich | 1 |
| Bradley Memorial, Southington | 2 |
| Bridgeport, Bridgeport | 3 |
| Bristol, Bristol | 4 |
| Danbury, Danbury | 5 |
| Day-Kimball, Putnam | 6 |
| Greenwich, Greenwich | 7 |
| Griffin, Derby | 8 |
| Hartford, Hartford | 9 |
| Charlotte-Hungerford, Torrington | 10 |
| Johnson Memorial, Stafford Springs | 11 |
| Lawrence and Memorial, New London | 12 |
| Manchester Memorial, Manchester | 13 |
| Meriden-Wallingford, Meriden | 14 |
| Middlesex Memorial, Middletown | 15 |
| Milford, Milford | 16 |
| Mount Sinai, Hartford | 17 |
| New Britain General, New Britain | 18 |
| New Milford, New Milford | 19 |
| Norwalk, Norwalk | 20 |
| Park City, Bridgeport | 21 |
| Rockville General, Rockville | 22 |
| St. Francis, Hartford | 23 |
| St. Joseph, Stamford | 24 |
| St. Mary's, Waterbury | 25 |
| St. Raphael, New Haven | 26 |
| St. Vincent's, Bridgeport | 27 |
| Sharon, Sharon | 28 |
| Stamford, Stamford | 29 |
| University of Connecticut, Farmington | 30 |
| Waterbury, Waterbury | 31 |
| Windham Community Memorial, Willimantic | 32 |
| Winsted Memorial, Winsted | 33 |
| W.W. II Veterans Memorial, Meriden | 34 |
| Yale-New Haven, New Haven | 35 |

Table 1

HOSPITAL CHARACTERISTICS CONSIDERED IN EMERGENCY SERVICES CAPABILITY CATEGORIZATION OF 35 SHORT-TERM ACUTE GENERAL HOSPITALS IN CONNECTICUT

I. Emergency Department Characteristics
  A. Access to Hospital-Emergency Department Complex
  B. Staffing
  C. Plant Layout
  D. Equipment
  E. Policies
  F. Communications

II. Characteristics of Hospital Operating Emergency Department
  A. Backup Medical Staffing
  B. Physical Plant
  C. Support Services
  D. Policies

> The Standard Emergency Service is capable of treating most individuals with real or apparent emergency medical conditions. In certain instances of critical illness or injury, definitive treatment may require transfer of the patient to another facility after initial evaluation and preliminary resuscitation.
>
> A Major Emergency Service can perform all the functions of a Standard Emergency Service. In addition, its manpower and/or service capabilities allow treatment of all but the most unusual emergency conditions or the accommodation of larger number of individuals in a given period of time.
>
> A Comprehensive Emergency Service can perform all the functions of a Major Emergency Service. A Comprehensive Emergency Service's capability extends to provision of definitive treatment of all individuals with any real or apparent emergency medical condition, except under extraordinary circumstances (e.g., disaster).

The touchy task of placing individual hospitals in their respective levels required particular attention to the adequacy of our data base and to close communication with the hospitals. In addition to the study of hospital emergency services to which I have previously alluded, the knowledge of individual Task Force members was of critical value. Once the Task Force had tentatively assigned all hospitals to their categories, each hospital was requested to assess the category assigned to it in terms of its appropriateness. Out of this process arose the need for six site visits to hospitals to assess their status by personal observation. In addition, it became clear that one hospital did not conform to criteria for a Standard Emergency Service in its emergency service physician staffing and stated that it could not do so. As a result, the Task Force was obliged to delineate criteria for hospital emergency service capability which were felt to be minimal to allow a hospital emergency service to continue to operate in Connecticut. Since the hospital in question met these minimum emergency service criteria, it was placed in a fourth hospital category designated Limited Emergency Service.

Final assignments of hospitals to their categories were completed in December, 1975 (Table 2). Ten hospitals were placed in the Standard level; 15 hospitals were categorized as Major, and 9 hospitals were felt to be Comprehensive. As previously noted, one hospital fell into a Limited category. The categorization document[4] was submitted to the governor-appointed Connecticut Advisory Committee on Emergency Medical Services, called into being by the new Connecticut Emergency Medical Services Act. The Connecticut Advisory Committee approved the categorization and submitted it to the Connecticut Office of Emergency Medical Services.

Table 2

INVENTORY CATEGORIZATION
OF
CONNECTICUT HOSPITAL EMERGENCY SERVICES

*Standard Emergency Service*

1. W. W. Backus
2. Bradley Memorial
3. Day-Kimball
4. John Dempsey
5. Griffin
6. Johnson Memorial
7. New Milford
8. Rockville General
9. Winsted Memorial
10. W.W. II Veterans Memorial

*Major Emergency Service*

1. Bristol
2. Danbury
3. Greenwich
4. Charlotte Hungerford
5. Lawrence and Memorial
6. Manchester Memorial
7. Meriden-Wallingford
8. Middlesex Memorial
9. Milford
10. Mount Sinai
11. Norwalk
12. Park City
13. St. Joseph
14. Stamford
15. Windham Community Memorial

*Comprehensive Emergency Service*

1. Bridgeport
2. Hartford
3. New Britain General
4. St. Francis
5. St. Mary's
6. Hospital of St. Raphael
7. St. Vincent's
8. Waterbury
9. Yale-New Haven

*Limited Emergency Service*

1. Sharon

By this time it had become apparent that categorization was becoming even more complex than had originally been conceived. David R. Boyd, M.D., Director of the Division of Emergency Medical Services in the Federal Department of Health, Education and Welfare (DHEW), had proposed "vertical" and "circular" categorization, as well as the "horizontal" form in which our effort to date might be classed.

Inasmuch as I had now been appointed Vice-Chairman of the Connecticut Advisory Committee on Emergency Medical Services, I agreed to organize another task force to push categorization further.

The composition of this new task force, which was to be designated the Task Force on Care Capability, was determined by asking each hospital previously categorized to send a professional representative.

The Task Force began its deliberations in May, 1976, and set as its tasks 1) determination of hospital capabilities in the care of seven critical emergency medical problems and 2) the identification of hospitals, recognized by patient transfer patterns within the state, with apparent particular expertise in the total management of these critical emergency medical problems.

The seven emergency medical problems were selected because of the high priority given them by DHEW. They were:

Multiple system injury
Cardiac emergency
Critical burn
Major central nervous system injury
Acute intoxication
Psychiatric emergency
Pediatric emergency

In order to obtain information beyond that already gathered at the time of the original hospital categorization, concerning hospitals' care capability relating to these problems, the Task Force developed listings of inventory criteria which were held to be optimal for the definitive management of each problem.

The seven listings were sent to each hospital's executive officer accompanied by a covering letter and a brief questionnaire asking that the hospital state 1) whether it conformed to the criteria listed for each problem and 2) if it had special capability in the total care of patients with each problem.

A second questionnaire was developed to assess transfer patterns, among hospitals categorized, for patients with the seven problems under study. Each hospital was asked whether patients with these problems were transferred for any reason; in addition, it was asked to list hospitals to which patients were transferred. Finally, each hospital was asked to state its willingness and ability to accept patients with the problems under study from other hospitals. This questionnaire and a covering letter were sent to each hospital's executive officer.

When the responses to the questionnaires had been obtained, tabulated, and evaluated, the Task Force devised the categorization framework into which individual hospitals could be placed. It was agreed that each hospital should be categorized according to its care capability related to each emergency medical problem under study. Accordingly, three categories of hospitals, A, B, and C, were defined:

> A Category A hospital does not conform to inventory criteria held to be optimal for the definitive management of the emergency medical problem addressed. It would be expected that patients most seriously ill with the medical problem in question might require transfer to another hospital, after initial stabilization, for optimal comprehensive care.
>
> A Category B hospital conforms to inventory criteria held to be optimal for the definitive management of the emergency medical problem addressed. It would be expected that virtually all patients admitted with this medical problem can be and are managed at this hospital, patients requiring transfer only rarely. Transfers of patients to this hospital from other hospitals might also occur.
>
> A Category C hospital conforms to inventory criteria held to be optimal for the definitive management of the emergency medical problem addressed. It would be expected that all patients admitted with this medical problem can be and are managed at this hospital. A Category C hospital has also been designated by at least three other hospitals as a hospital to which patients with this medical problem are transferred when transfer is deemed appropriate.

Table 3 shows the categorization of the 35 hospitals. Figures 3-9 illustrate in diagrammatic fashion the transfer patterns, among hospitals studied, for patients with each medical problem.*

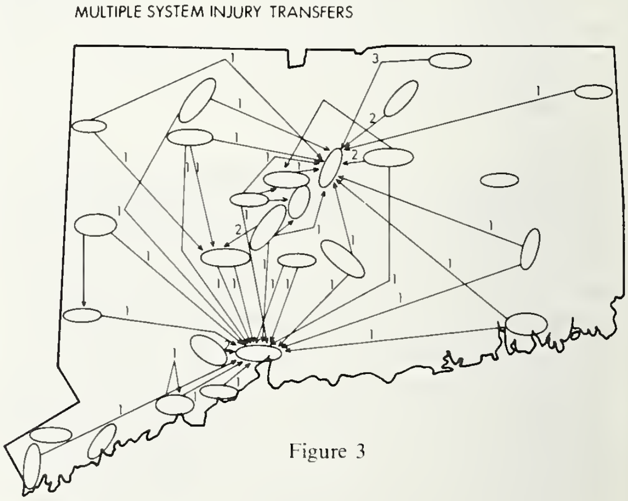

Figure 3

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*Numbers associated with arrows leading to cities in which more than one hospital is located signify the number of hospitals *to which* patients are transferred.

## Table 3

CARE CAPABILITY CATEGORIZATION

| *Hospitals* | *Multiple System Injury* | *Cardiac Emergency* | *Critical Burn* | *Major Central Nervous System Injury* | *Acute Intoxication* | *Psychiatric Emergency* | *Pediatric Emergency* |
|---|---|---|---|---|---|---|---|
| Backus | A | B | A | A | B | A | B |
| Bradley Memorial | A | B | A | A | B | A | B |
| Bridgeport | B | B | C | B | B | B | C |
| Bristol | B | B | B | B | B | B | B |
| Danbury | B | B | B | B | B | B | B |
| Day Kimball | A | B | A | A | B | B | B |
| Greenwich | B | B | A | B | B | B | B |
| Griffin | A | B | A | A | B | A | B |
| Hartford | C | C | C | C | C | C | C |
| Charlotte Hungerford | A | B | B | A | B | B | A |
| Johnson Memorial | A | B | A | A | B | A | B |
| Lawrence and Memorial | B | B | A | B | A | A | B |
| Manchester Memorial | B | B | B | B | B | B | B |
| Meriden-Wallingford | B | B | B | B | B | B | B |
| Middlesex Memorial | A | B | A | A | B | B | B |
| Milford | B | B | B | B | B | B | B |
| Mount Sinai | B | B | B | B | B | B | B |
| New Britain General | B | B | B | B | B | B | B |
| New Milford | A | B | A | A | B | A | B |
| Norwalk | B | B | B | B | B | B | B |
| Park City | B | B | A | B | B | B | B |
| Rockville General | A | B | A | A | B | B | B |
| St. Francis | C | C | B | C | B | B | C |
| St. Joseph | B | B | B | B | B | B | B |
| St. Mary's | B | B | B | B | B | B | B |
| St. Raphael | B | C | B | B | B | C | B |
| St. Vincent's | B | B | B | B | B | B | B |
| Sharon | A | A | A | A | A | A | A |
| Stamford | B | B | B | B | B | B | B |
| University of Connecticut | A | B | A | A | B | A | C |
| Waterbury | C | B | B | B | B | B | B |
| Windham Community Memorial | B | B | B | B | B | B | B |
| Winsted Memorial | A | B | A | A | B | A | B |
| W.W. II Veterans Memorial | A | B | A | A | B | A | B |
| Yale-New Haven | C | C | C | C | C | C | C |

CARDIAC EMERGENCY TRANSFERS

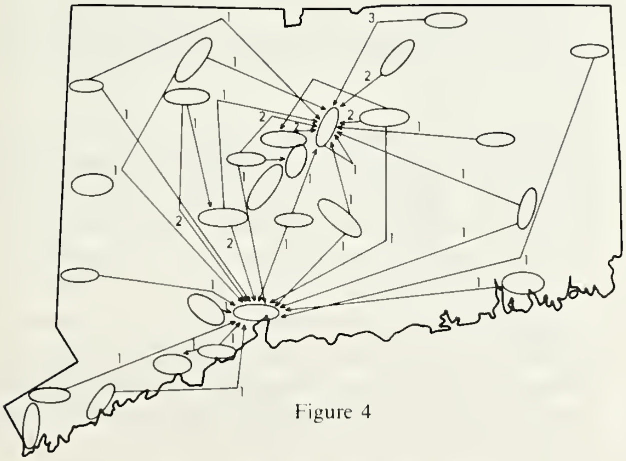


Figure 4

CRITICAL BURN TRANSFERS

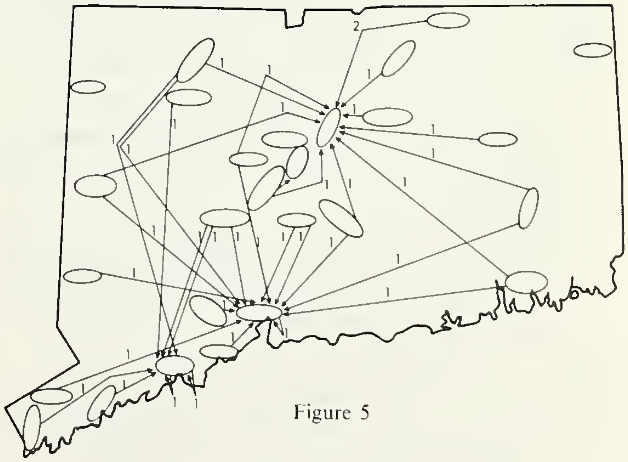
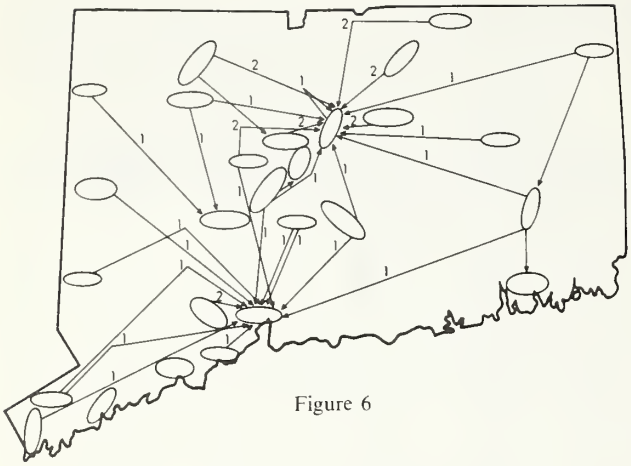
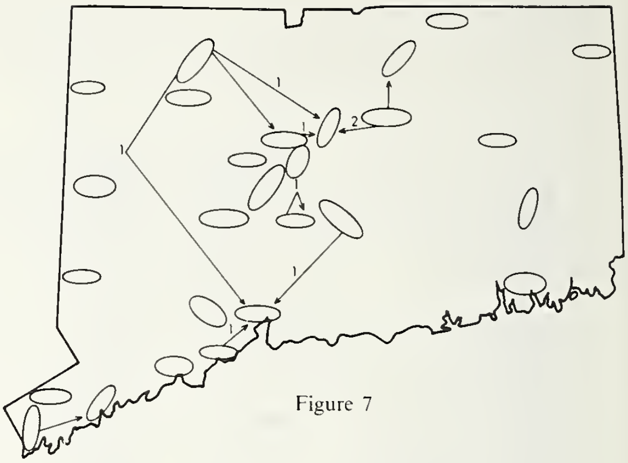


Figure 5



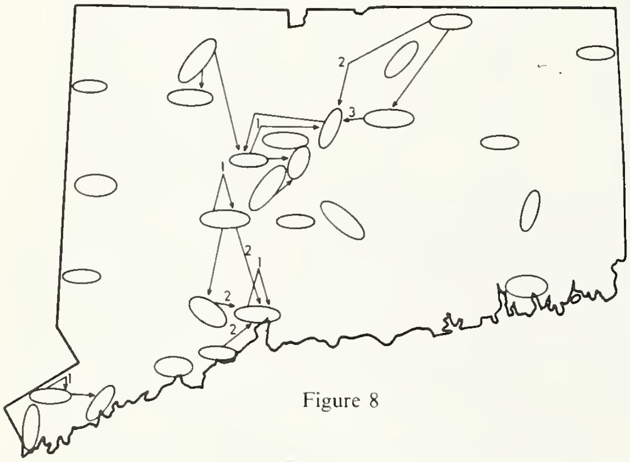
MAJOR CENTRAL NERVOUS SYSTEM INJURY TRANSFERS

Figure 6



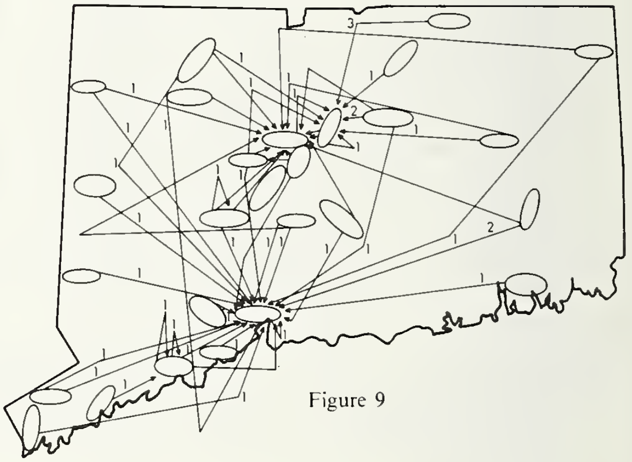
ACUTE INTOXICATION TRANSFERS

Figure 7



PSYCHIATRIC EMERGENCY TRANSFERS

Figure 8



PEDIATRIC EMERGENCY TRANSFERS

Figure 9

The categorization of care capability[5] was submitted to the Connecticut Office of Emergency Medical Services in November, 1977.

Where does Connecticut go with categorization from this point? Perhaps the best way to express the views of those of us who have been most involved is to quote from the statement[6] we developed in May, 1978, for inclusion in the State Health Plan:

"1. Categorization standards and procedures previously recommended to the Office of Emergency Medical Services should be adopted and implemented.

2. Plans to continually validate and update categorization schema should be developed by the Office of Emergency Medical Services with the assistance of the regional EMS Councils and the organizations being categorized.

3. An intensive program of information and education to promote understanding and proper utilization of categorized organizations should be undertaken.

4. The Office of Emergency Medical Services should develop guidelines for medical treatment protocols with the assistance of a Task Force of appropriate persons that will establish minimal standards for transfer and acceptance of patients by July 1, 1979."

And that has been the process of categorization of hospital emergency services in Connecticut. What is its significance?

Thus far, the only tangible benefit of categorization to us seems to be that the presence of categorization documents included in grant applications may be helping to obtain federal funds for several regions in the state; hopefully, our effort may have substantially more value than that.

Connecticut is a small state, and it has no sprawling urban complexes. Only two cities, Hartford and Bridgeport, have more than two hospitals. On the other hand, access to hospitals is remarkably easy for the citizens of the state. Moreover, it appears that the quality and quantity of emergency services in hospitals are, by comparison with many parts of the country, outstanding. While we recognize areas in which improvement must occur, it does not seem that we require any revolutionary changes to accomplish what categorization was devised to do, in our view, namely:

1. encourage the proper performance of emergency care by properly trained individuals in a proper environment;
2. prevent duplication of specialized services within the emergency care system;
3. improve the capabilities of hospitals to provide effective emergency care for all patients served by the hospital.

For Connecticut, perhaps the most important facts uncovered by the categorization process are 1) that there seems little need for major funding to raise the level of capability of hospital emergency services at present and 2) that implementation of categorization will not be dramatic in its impact.

In our search for data, in the categorization of hospitals, and in analyzing transfer patterns, we were struck by the orderliness of the system and by the lack of surprises we encountered. Perhaps we should have expected this in a state known for a tradition of medical sophistication and a strong hospital association, but it was nonetheless of great interest to us.

Undoubtedly, the categorization process will be more difficult in other locales, and statewide categorization does not seem appropriate for many parts of the country; however, we found that, by involving the proper people in the process and by keeping wide-open lines of communication with all concerned, we could accomplish categorization without major fund expenditures and without having to rely only on what hospitals wished to say about themselves for a data base. This was by no means hospital self-categorization!

It may be that the most important aspect of the Connecticut categorization experience is that it shows one way that credible categorization can be accomplished without involving major upheaval in the hospital system. In that sense, it seems to be a viable model.

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## Hospitals Show Real Progress in Curbing COST ESCALATION

Doctors and hospitals are beginning to get a handle on the rising cost of hospital care, Paul W. Earle, executive director of the voluntary effort of organized medicine and hospitals to curb costs, declared.

Speaking at a national meeting of the Health Section of the Public Relations Society of America at Chicago, Earle said the professions are achieving their goal of reducing by 2 percent each year the percentage of cost rise.

In 1976 hospital costs increased by 19.7 percent, Earle said. In 1977 the rate of increase was pared to 15.6 percent. And for the first quarter of 1978 the rate of increase was only about 13 percent.

"Hospitals and physicians are tightening up. There's no doubt about it," Earle declared.

There have been more mergers, more sharing of services, a slowing of expanding hospital personnel. And the average length of stay—7.4 days in recent years—has been reduced to 7.2. In national terms this represents a substantial saving.

The voluntary cost containing effort is a joint endeavor of the American Medical Association, American Hospital Association and Federation of American Hospitals, with the cooperation of such other groups as Blue Cross-Blue Shield and the Health Insurance Association of America.

Earle, a vice president of the American Hospital Association, is executive director of the steering committee of the three organizations.

Speaking on the same program, William M. Cohan, representative of the American Medical Association on the steering committee, declared that the cost containing campaign has been aimed substantially at the chiefs of medical staffs of each hospital in the nation. The head doctors have been asked to institute cost control measures in their hospitals. "It is physicians who order patients into hospitals, who prescribe treatment, who order surgery, who order x-rays and lab tests. And the physicians are already cooperating in the drive to hold down the escalation of costs by voluntary means," Mr. Cohan said.—*New York State Journal of Medicine,* September 1978.

# Common Bile Duct Obstruction Caused by a Duodenal Diverticulum

AMBROSE ALFONSI, M.D., JANET B. DICKINSON, B.S.,
GARY BROWN, M.D. AND JOSEPH ARCANO, M.D.

The occurrence of symptoms that can be definitively related to duodenal diverticula and that require surgical intervention for alleviation of those symptoms is exceedingly rare. Sykes mentions 14 cases in literature prior to the presentation of his case in 1970.[1] The total number of reported cases was boosted to 17 in 1972 with the presentation of 2 cases by Neel.[2]

We wish to document a case of obstructive jaundice due to mechanical compression of the common bile duct by a large diverticulum of the second portion of the duodenum.

## Case History

A seventy-two-year-old white female was first seen in the emergency room four days following the initiation of severe nausea, vomiting and diarrhea and slight fever. Onset of symptoms, as described by the patient, was quite rapid, approximately 2 hours after having eaten out, and was highly suggestive of acute toxicity or viral gastroenteritis, since she had no history of food sensitivity.

Physical examination revealed a full, but non-tender abdomen with no masses or visceromegaly palpable. Examination of the eyes in natural light disclosed a slight, but distinct scleral icterus. The patient complained of general malaise and occasional right upper quadrant pain. A cholecystectomy had been performed approximately 35 years prior to the current onset of symptomatology. The patient had been apparently well until the present episode, although occasional epigastric pain and discomfort had been reported.

Admitting blood work revealed an electrolyte imbalance, apparently hypokalemic alkalosis accompanied by decreased values for sodium and chloride. The patient had a history of hypertensive cardiovascular disease with a controlled first degree AV block and controlled congestive decompensation. Admitting blood work also disclosed an alkaline phosphatase of 212 International Units (norm. 30-115U.); total bilirubin 3.6 mg% (norm. 0.2-1.2 mg%); SGOT 46U (norm. 0-41U) and SGPT 76 mU ml (norm. 0-43 mU ml). A hepatitis B surface antigen test was negative. Repeat blood work, done 4 days after admission, revealed the following: an increased alkaline phosphatase to 346 U, a total bilirubin of 2.8 mg%, a decreased SGOT to within normal limits and a slightly decreased SGPT to 68 mU/ml, still above the norm. At this time, physical exam of the patient revealed clinical jaundice over the body as well as scleral icterus.

An IV cholangiogram was done yielding a report of "non-visible gallbladder, compatible with previous cholecystectomy, and an unremarkable abdomen." Both upper and lower GI series revealed multiple diverticula. An especially large diverticulum (diameter of head on x-ray was 6.5 cm with a "stalk" 1.5 cm in diameter) (see Figure 1) arising in the periampillary area and extending in the direction of the common bile duct was noted. There were no definitive, specific soft tissue defects noted in the duodenum to suggest pancreatic pathology.

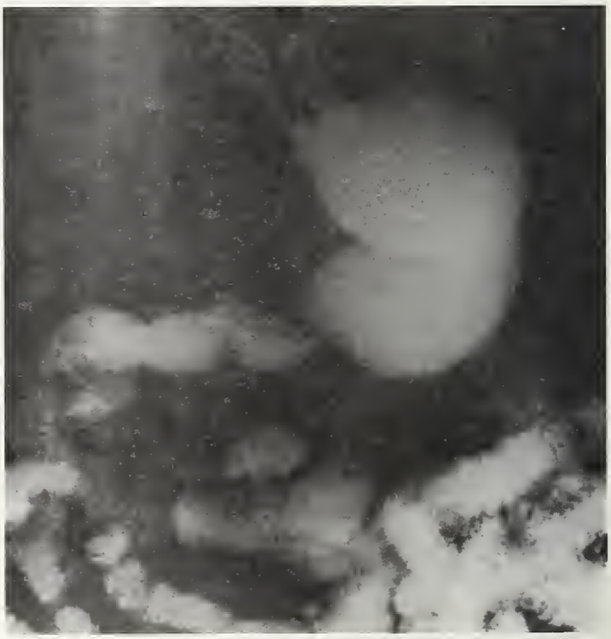

Figure 1

Operation was carried out with the presumptive diagnosis of obstructive jaundice due to non-radio-opaque gall stone or stones in the common bile duct. The surgery revealed an enlarged and inflamed common bile duct, dilated to approximately 2 to 3 times

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its normal diameter. A bulging diverticulum of the superior aspect of the second portion of the duodenum was found pressing on the inferior aspect of the common bile duct. The common bile duct was opened and explored. No stones were evident, so a T-tube was inserted and an operative cholangiogram was done which revealed an acutely medially angulated common duct and no stones. (See Figure 2). Accordingly the diverticulum was excised and the sutured stump was inverted.

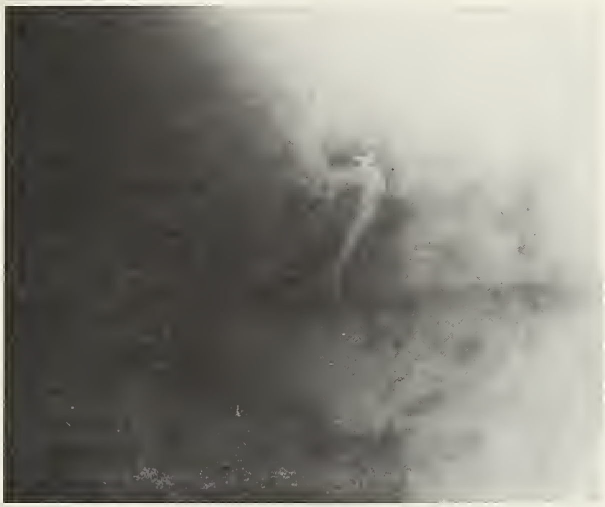

Figure 2

The patient experienced an unremarkable recovery. On the 8th day following surgery, a post-operative cholangiogram was taken revealing a much smoother, more normal course of the common bile duct with elimination of the angulation (see Figure 3). After removal of the T-tube, the patient was released to home and has been asymptomatic since then.

The patient was re-examined on April 18, 1978. She was asymptomatic. The repeat blood work revealed all studies to be within normal limits including the previously elevated alkaline phosphatase and bilirubin.

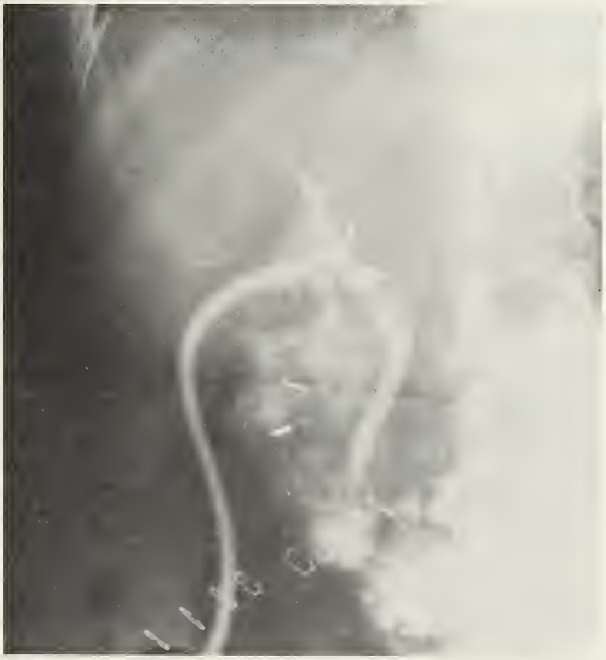

Figure 3

## Discussion

It seems likely that the patient suffered an acute viral gastroenteritis which infected the diverticulum. Inflammation of the stalk-like diverticular attachment to the duodenum produced some degree of obstruction and stasis of its contents with a subsequent build up of pressure within the diverticulum accompanied by an increase in size, which then impinged upon the common bile duct. Supporting this theory are the anatomical location of the diverticulum in relation to the common bile duct and the tissue pathology of the diverticulum itself which showed evidence of acute and chronic inflammation. The consecutive cholangiograms which show receding angulation of the common bile duct at the site of the diverticular impingement, upon removal of the offending diverticulum, bear this out. (Figures 2 and 3)

Supporting the diagnosis and treatment of this case are various reports of this unusual occurrence. Many of these cases report multiple diverticula of the duodenum and over 35% of those cases of multiple duodenal diverticula have concomitant diverticulosis of the colon.[3] Another common anatomical finding is that a large percentage of true diverticula of the duodenum, or those that contain both serosa and mucosa, arise on the concave aspect of the second portion of the duodenum,[1 3 4 5] especially in the periampullary region. These diverticula tend to be acquired due to weakness in the muscular wall of the gut,[5] in contrast to false diverticula which are generally only mucosa and are congenital.[1 3 4 5]

Because a long-standing or chronic course with continued complaints after cholecystectomy also seem to be common factors relating to diverticula which ultimately lead to obstruction of the common bile duct with jaundice, a "post-cholecystectomy" syndrome has been proposed by Neel.[2] This syndrome consists of a recurrence or persistence of symptoms after cholecystectomy and generally causes the surgeon to consider the possibility of overlooked, non-radio-opaque stones in the common bile duct. Our case presented in this manner as the pre-operative or presumptive diagnosis was obstructive jaundice due to obstruction of the common bile duct by non-radio-opaque stones. The difference between our case and the others mentioned with regard to this "syndrome" was that the time interval between cholecystectomy and recurrent symptoms was 35 years. The "syndrome" related cases had histories in which this interval was usually 6 years or less.

## Surgical Procedure

There has been mention in the literature of many serious complications using the type of surgical procedure that was employed in this case. Sykes[1] states that, "the apparent draw-back to this type of surgery (excision of offending diverticulum) is the possibility of leakage of pancreatic proteolytic enzymes from the suture line which can often be a fatal complication." He goes on to recommend various other more radical surgical procedures, such as a combination of diverticulectomy with gastroenterostomy and pyloric occlusion, or jejunostomy and gastrostomy, also choledochoduodenostomy, which involve a longer duration of surgery and possible or probable secondary surgical intervention after healing. Furthermore, and, perhaps, more important is that Desmond and Heald,[3] who were referred to by Sykes, made their recommendations in reference to repair of ruptured duodenal diverticula. The fact that we are dealing with relatively healthy tissue with a good blood supply would seem to improve the probability of recovery without the complications that would accompany rupture of small bowel diverticulum into the peritoneum. A repair of highly friable tissue that has recently ruptured allowing the escape of pancreatic enzymes into the abdominal cavity seems more likely to be associated with seepage along the suture line if not outright post-operative rupture. The uneventful recovery of our patient would favor a simple diverticulectomy for those patients whose conditions were similar. A case presenting with multiple adhesions which would require tedious dissection might be better handled by by-pass or cholecystojejunostomy.[1]

### Conclusion

It seems apparent from the presentation of this case and subsequent research of other reported cases, that, although duodenal diverticula are generally asymptomatic, they must not be ruled out as a possible cause of obstructive gall bladder disease, obstructive jaundice, or seemingly recurrent symptomatology following cholecystectomy. Furthermore, although a conservative approach to the question of resection of duodenal diverticula is wise, surgical removal should not be eliminated from consideration with the advent of symptomatology. The possibility of surgical cure should be considered and weighed against the complications and disadvantages of such surgery.

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# The Dying Hip in the Healthy Patient: Diagnostic Problems and Therapeutic Misadventures

ROBERT N. MARGOLIS, M.D.

### Introduction

One of the most common symptom complexes seen in orthopedic practice is that of pain and limp about the hind quarter, worsened by standing, walking and change of position and relieved by rest. These complaints are often associated with radiation to the buttock proximally and the knee distally. Most doctors in clinical practice have seen many of these patients and most often the source of pain is a mechanical derangement of the joints of the low back, particularly of the intervertebral discs. The symptom of sciatica is so common in modern man that a patient will often volunteer it by name to the examining physician.

A less common source of buttock and thigh pain is the hip joint. As an orthopedic surgeon, I have often been humbled by my difficulty in deciding whether the patient's pain comes from the hip or the back. The frequency with which primary hip pathology has been

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erroneously diagnosed as discogenic sciatica and unsuccessfully treated as such must be appreciable. The author had little difficulty collecting six patients who were thought to have back rather than hip pathology, five of whom actually were subjected to laminectomy for disc before their true diagnosis was appreciated.

### The First Mistake

The sensory nerves supplying any joint are branches of mixed sensorimotor nerves of the muscles moving that joint. Thus the sensory fibers for the hip joint are branches of the sciatic, femoral and obturator nerves. The painful stimuli arising within or about the hip joint will be felt in the buttock and posterior thigh (sciatic nerve L4,5 S1,2), trochanter and anterior thigh (femoral nerve L2,3,4) and groin and medial thigh (obturator nerve L2,3,4). The intensity with which one or more of these sensory branches reports nociceptive stimuli from the hip joint, its synovial membrane and capsule, seems variable with every patient and perhaps the type of hip pathology. For instance, children with slipped capital femoral epiphyses, Legg-Perthe's disease and other painful hip conditions will almost universally complain of pain primarily in the distal thigh anteriorly (femoral nerve). Any orthopedic surgeon will attest to having seen children referred to him for evaluation of knee pathology who limp into his office with a set of normal knee films. The patient, the family and the referring physician are all surprised when told that the source of pain is the hip joint. With equal frequency we have seen adult patients whose hip pain is primarily in buttock and posterior thigh (sciatic nerve) distribution who are referred for evaluation of back pathology. According to Hakelius and Hindmark[1] only 15% of this group will have completely normal back x-rays whereas the remaining 85% will have some x-ray abnormality.

### Physical Findings Common to Hip and Back Conditions Which Tend to Cloud the Waters

Certain points in the history and physical findings are common to both low back and hip pain and tend to confuse both patient and physician. This is particularly true when the hip pathology consists of segmental avascular necrosis in a previously normal hip. This slowly progressive condition was the diagnosis in four of the six patients I report. Pain from both back and hip is worsened by activity and relieved by rest. Painful limp, common to both conditions, is often difficult to characterize as to biomechanical source. Trunk asymmetry, which is easy to notice and often pointed out to the patient by friends or family, is, for many of us, hard to sort out. Is the slightly twisted, tilted patient demonstrating a pelvic tilt from involuntary flexion adduction contracture of the hip joint, or a lateral trunk tilt (sciatic scoliosis) arising in the low back?

On physical examination, the doctor, having reproduced the patient's pain by the classic straight leg raising test, may forget that he is also flexing the painful hip.

Having reached an erroneous diagnosis of disorder of the low back, the physician and his patient may further confuse each other by a temporarily favorable response to treatment. Unquestionably, rest, heat, analgesics, muscle relaxants, anti-inflammatory agents, traction, etc. will bring improvement, sometimes dramatic, in symptoms arising from either hip or back. However, with attempted resumption of normal activities symptoms usually return and so does the patient. The doctor is then confronted with a patient who fulfills one of the criteria for surgical intervention in disorders of the back: failure of conservative treatment. This patient may then undergo myelographic study, and if myelography shows an abnormality, laminectomy and discectomy may be done.

### Can the Myelogram Lie?

While most of us consider myelography a highly accurate and conclusive indication of active and symptomatic disc pathology, we should remember that it has been shown that the lumbar myelogram can be interpreted as "positive" in from 24 to 50% of asymptomatic adult patients with no history of back trouble whatsoever. Hitselberger and Witten,[2] for instance, studied the lumbar spine of 300 adult patients with no present or past history of back pain who were undergoing myelography for posterior fossa lesions and found significant lumbar disc defects in 71. McCrae[3] studied 40 asymptomatic patients age 50 to 59 undergoing myelography for cervical problems and found 23 in whom the lumbar myelogram could be read as positive. He further dissected the lumbar spines of 18 cadavers, all of whom were asymptomatic with reference to the back during life, and found large disc protrusions in 7.

Thus, it is not surprising that most of the patients I have collected had "positive" myelograms but were not relieved of their pain by back surgery, since the source of that pain was not in the back. In fact, the only patient who did not undergo back surgery was a workmen's compensation case who was lucky enough to have had two negative myelograms (Case 1 P.R.). On the other hand, Case 6 (A.P.) had not one but two back operations, one year apart at the L4,5 space on each side of the midline, for what can reasonably be assumed to be pain from progressive necrosis of first one, then the other hip. This man, not surprisingly, has refused reconstructive hip surgery. The six cases collected are summarized in Table 1.

### Hopefully Helpful Hints

The easily confused entities of spondylogenic and coxagenic leg pain can be more accurately sorted out

Table I

| *Case* | *Age/sex at onset symptoms* | *Presenting complaints* | *Significant past history* | *Myelogram interpretation* | *Interval from presentation to laminectomy* |
|---|---|---|---|---|---|
| #1 P.R. | 32-M | L. buttock and lat. thigh pain | EtOH abuse | negative | no laminectomy |
| #2 R.D. | 35-M | L. buttock, thigh knee pain | EtOH abuse | HNP L4/5 left | 7 mo. |
| #3 J.W. | 41-F | L. buttock, thigh groin pain | EtOH abuse | HNP L4/5 left | 1 mo. |
| #4 R.W. | 53-M | R. hip pain with limp | steroid therapy (ulcerative colitis) | equivocal for HNP | 3 mo. |
| #5 H.F. | 59-M | R. hip pain | lam. for disc 12 years before ? EtOH abuse | recurrent HNP L4/5 right | 2 mo. |
| #6 A.P. | 62-M | R. hip pain | osteoarthritis of hips, bilateral | HNP L4/5 bilateral | 1 yr. to 1st lam.<br>2 yrs. to 2nd lam. |

*(continued)*

| *Case* | *Interval from myelogram/laminectomy to diagnosis of hip disorder* | *Final Diagnosis* | *Hip surgery* |
|---|---|---|---|
| #1 | 2 yr. | Bilateral avascular necrosis (AVN) of hips | mold arthroplasty, bone grafts, revision molds X2, total hip replacement X2 (6 operations) |
| #2 | 2 yr. 6 mo. | AVN left hip | hemiarthroplasty, then THR |
| #3 | 1 yr. | AVN left hip | hemiarthroplasty L. |
| #4 | 1 yr. | AVN right hip | THR |
| #5 | 1 yr. | AVN in osteoarthritic hip-right | THR |
| #6 | 1 yr.<br>(Dx of AVN prior to laminectomy) | AVN in osteoarthritic hips-bilateral | none (refused) |

by a knowledge of points on history and physical which distinguish the two.

None of these points are by any means pathognomonic but they have proved helpful to me in the past.

### History

1. Relief of pain by sitting. This suggests hip rather than disc pain. Nachemson and Morris[4] have shown that the intradiscal pressure is surprisingly high in the sitting position whereas the act of sitting both relieves hip loading and brings the painful hip into a more comfortable position of semiflexion.

2. The pain is worse during the first 10 to 20 steps after a period of sitting. This phenomenon suggests synovial joint (ie. hip in our discussion) pain. It is due to the temporary breakdown of the surface lubrication system of synovial joints at rest and the necessity of relubricating the joint surfaces as motion and weight bearing are resumed.

3. Anterior thigh rather than posterior or "deep" thigh pain. This distribution is much more common in hip than back pain since involvement of the lumbar roots contributing to the femoral nerve is associated with the relatively rare L3 disc herniation.

4. Pain referred to the anterodistal femur or suprapatellar area of the knee. Again for the neurologic reason mentioned above this is much more commonly hip than back in origin. Mention has already been made of this particular phenomenon in children which has led to the orthopedic aphorism "pain in the knee, think of the hip."

### Patient Groups at High Risk for Avascular Necrosis

Tip-offs to the possible diagnosis of avascular necrosis of the hip are a history of alcohol abuse, prolonged steroid and/or immunosupressive therapy and diabetes. Less common etiologies are hemoglobinopathies, lipidoses, and hemophilia.[5 6 7 8] Obviously, the final common pathway to death of the femoral head is some sort of vasculitis. In our group of six patients, four had histories of alcohol abuse and one of prolonged systemic steroid therapy. Thus, only one out of six was not in a high risk group.

### Differentiation on Physical Exam

The following physical findings have been of use in pointing to a hip rather than back condition as responsible for thigh pain.

1. Passive rotation of hip joint, patient supine (ie. rolling the leg inward and outward). This motion will have no effect on intervertebral discs or inflamed lumbar roots. It will often reproduce the patient's hip pain by stretching the inflamed capsule and synovial membrane.

2. "Two-stage straight leg raising test." This maneuver tries to separate hip motion from sciatic stretch. Stage I: Patient supine, hip flexed 90 degrees with knee flexed 90 degrees then hip rotated. Stage II: From this position of 90 degrees hip and knee flexion the knee is extended to zero which stretches the sciatic nerve but produces no further effect on the hip joint. If the patient's pain is reproduced by Stage I and not worsened by Stage II, hip pathology is strongly suggested. If pain is absent or minimal at Stage I but produced by Stage II, one should consider the low back as the site of pain.

3. Thigh atrophy versus calf atrophy. In painful conditions of the hip some degree of thigh atrophy, often no more than a centimeter or two, will rapidly develop. Calf atrophy on the other hand in the absence of thigh atrophy is almost universally associated with the back (L4,5 S1 roots). Again the exception to this rule is the atypical upper lumbar disc.

4. Gluteus medius (Duchenne) limp. This patient with any painful condition of the leg, from a pebble in his shoe to an osteosarcoma of the femur, will limp. However, the shift of body weight over the painful hip, most easily observed by watching the ipse lateral shoulder drop to the side of the pain on stance phase of gait is easy to pick up. The limp is markedly different from the limp of a patient with discogenic sciatica who deviates the trunk to the side opposite his pain and tends to hold his shoulders immobile in his effort to avoid unnecessary intervertebral joint motion.

### Summary and Conclusions

This paper has discussed points in the differential diagnosis of two sites of origin of a very common clinical symptom and sign complex. All the cases reported here were ultimately shown to have avascular necrosis of the femoral head as the source of their pain. Obviously there are dozens of other conditions in and around the hip joint which can lead to similar confusion.[9] Idiopathic avascular necrosis of the hip is particularly treacherous to diagnose because of the long interval between the onset of symptoms and the appearance of easily identified x-ray changes in the hip, which can range from a few months to three years.[10]

### Recommendations

It is recommended that the entity of hip disease in general and avascular necrosis of the hip in particular be considered in a differential diagnosis of upper thigh pain in adults and that the distinguishing aspects of history and physical findings outlined above be sought. In addition it is suggested that x-ray studies of the lumbar spine include an AP projection of the pelvis on a 14 by 17 film taken with the hips in 20 degrees of internal rotation so that a comparative evaluation of both femoral heads and necks can be made. Many x-ray departments include, in addition to standard AP and lateral views of lumbar spine, further views to examine the sacrum and sacroiliac joints but balk at including an AP projection of the pelvis for hip joints, although the hips are a much more common source of trouble than the sacrum and sacroiliac joints. Also, for cases in which there is some clinical doubt as to the site of origin of upper thigh pain, nuclear scanning techniques can often help by demonstrating an area of avascularity in the femoral head which is normal on plain x-rays.

I am indebted to my associate, Dr. Alan Goodman, for Case 2 and my colleague, Dr. Earl Rhoades, for Case 6.

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# Instrumentation of a Telemetry System for Monitoring Fetal and Neonatal Cardiac Activity

ORVAN W. HESS, M.D. AND WASIL LITVENKO, E.E.

The importance of careful monitoring of cardiac activity of the fetus for the elucidation of its well-being and the detection of untoward reactions to environmental factors, drugs, maternal disease and labor is widely accepted. Recognition of the limitations of stethoscopic sampling of fetal heart rate as a tool for evaluating the status of the fetus and the need for improved methods stimulated physicians and engineers in the effort to make available instrumentation specially designed for this purpose.[1] [2] The introduction of electronic techniques for detection and continuous recording of normal and abnormal patterns of fetal heart activity has been one of the notable advances in the past decade. Reports[3] [4] based on extensive data comparing infant outcome indicate a marked decrease in mortality and morbidity when electronic apparatus has been used as an adjunct to obstetrical and pediatric care. An important indirect spin-off effect leading to improved perinatal care has resulted from its role in providing a clearer understanding of the parameters of normal fetal physiologic relationships and the demonstration of pathologic manifestations.

The focus of much effort in recent years has been on the development of electronic equipment which will not only provide reliable measurement of fetal heart rate, and other significant parameters associated with labor, but will also fulfill the practical demands for usefulness in clinical applications.[5]

Standard available equipment using wire cabling offers some disadvantages: it is (1) somewhat cumbersome and space-consuming, (2) difficult to move about, (3) requires proximity to electrical outlets, and (4) a source of apprehension for some patients. Telemetry offers some advantages: (1) The apparatus is small and of light weight and may be battery-powered, (2) movement of patients and equipment is easier, (3) the patient can be monitored from a remote location, during administration of flammable anesthetics, delivery and operative procedures, and (4) electrical isolation of the patient is complete.

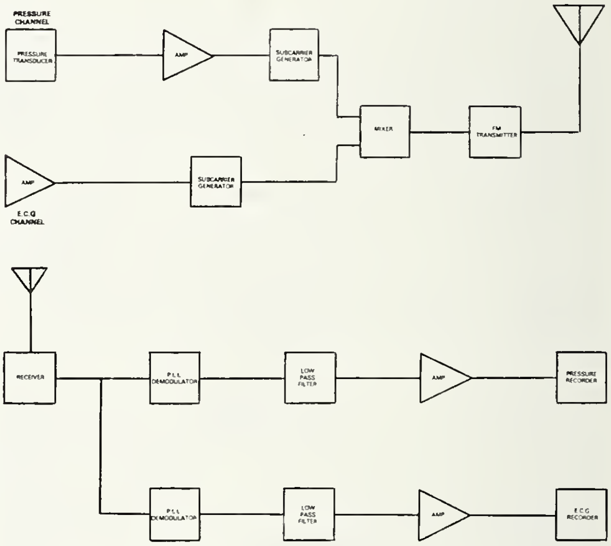

Figure 1
Block Diagram of System for radio-telemetry of fetal heart activity and uterine pressure.

During the course of evolution of a variety of electronic techniques, progress has to a large extent been dependent on the development and incorporation of technologic innovations in circuitry and miniaturized components.

We have previously described[6] a two-channel radio-telemetry fetal monitoring system, employing crystal-controlled transmit-receiver apparatus of an intermediate size capable of transmitting fetal ultrasonic cardiac signals, fetal electrocardiogram and uterine pressure obtained by means of external or internal transducers. Experience with that apparatus has shown it to be clinically applicable for both invasive

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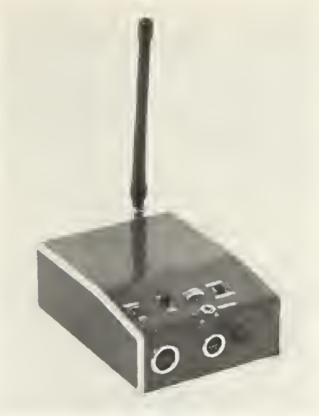

Figure 2
Transmitter for telemetry of fetal heart activity by ultrasound and electro-mechanical techniques.

and non-invasive techniques. The use of ultrasound for the detection of fetal heart activity on the basis of the Doppler principle[7] broadened the range of applications of electronic techniques employed for monitoring fetal status. With appropriate transducers placed on the abdominal wall it is now possible to obtain a continuous record of the fetal heart rate prior to rupture of the membranes. Surveillance in this manner allows assessment of the fetal condition and has been shown to have special value in the clinical management of patients when high risk of compromise of fetal reserve or other complications exists. During investigation of this system,[7] using ultrasound transducers which incorporate multiple crystals, useful tracings were obtained in 75-80 percent of cases during "stress tests" and early labor. Failure is more dependent on such factors as unusual position or activity of the fetus, interposition of the placenta, or excessive amniotic fluid than on malfunction of the apparatus.

The purpose of the present report is to describe newly developed apparatus designed to accomplish further reduction in size of the transmitter and receiver employed in a telemetry system for monitoring the fetal and neonatal electrocardiogram and uterine pressure.

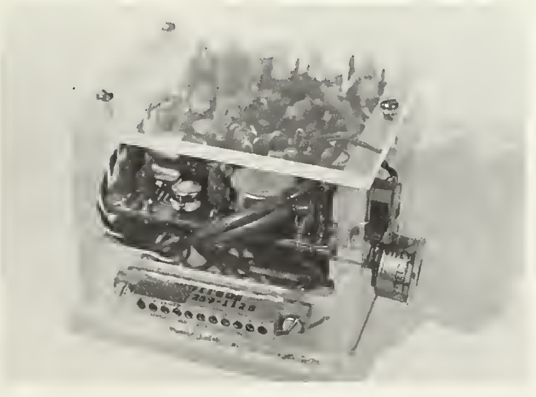

Figure 3
Current transmitter for radio-telemetry of the fetal-neonatal electrocardiograms and uterine pressure.

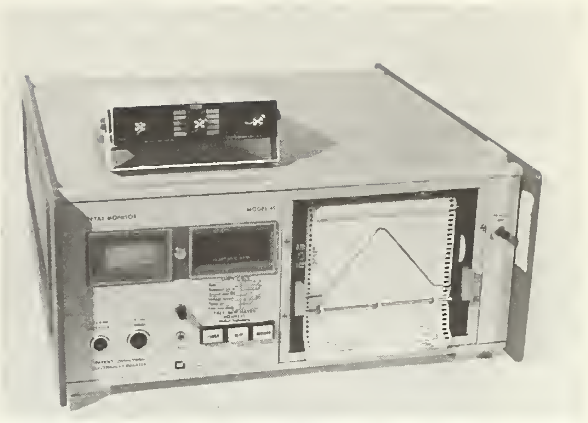

Figure 4
Apparatus presently used in system of detection and recording fetal and uterine pressure.

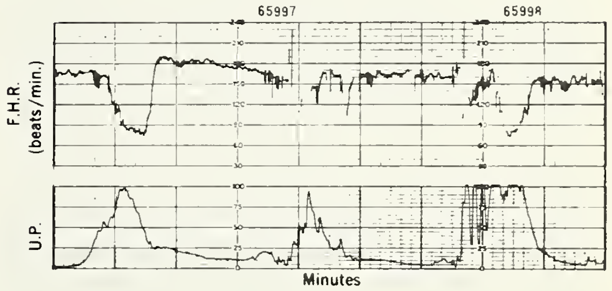

Figure 5
Tracing of fetal heart rate telemetered during use of current transmitter. Patient in late labor, "pushing" just before delivery.

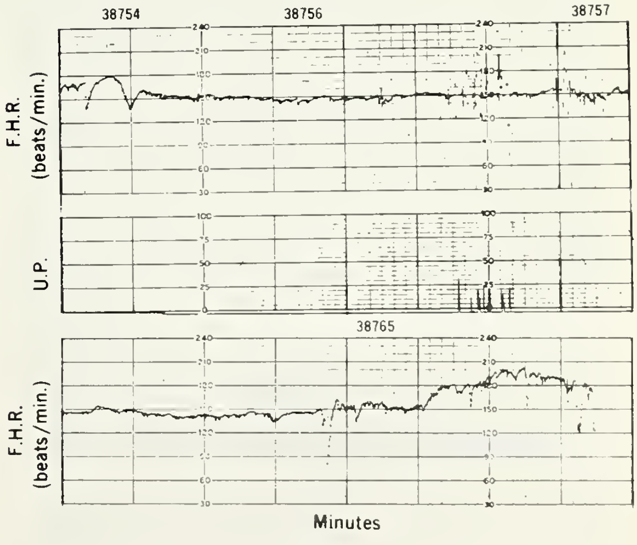

Figure 6
Tracing of fetal heart rate and uterine pressure recorded during telemetering 200 feet from a patient in active labor.

The present transmitter, which can be made even more compact, is of small size, weighs 180 grams and is readily moveable. It may be attached to a lightweight belt about the patient's abdomen alongside a small tocograph for simultaneous transmission of alterations in pressure associated with uterine contractions. If desired, it may similarly be secured about the thigh along with a standard leg-plate and pressure transducer. In both instances, only short insulated wire connections with scalp or abdominal electrodes are required. Variations in intrauterine pressure obtained by means of a small type strain gauge or a direct intrauterine sub-miniature transducer are transmitted over the same channel. Tests of the apparatus have been conducted in a variety of clinical conditions. When used with standard scalp electrodes, in 30 of 35 instances tracings of fetal heart activity equivalent to or better than those recorded by traditional methods using wire cabling were obtained. Failures were due to faulty connections with scalp,[2] imperfect grounding[1] and low battery power.[2] The distance of transmission varied from 10 to 300 feet between various rooms and floors in the hospital. The system allows the patient to move about more freely and be transported to the delivery room without interruption of data transmission. Monitoring has been continued during anesthesia and operative procedures of cesarean section up to the moment of delivery of the vertex. Records have been obtained throughout the second stage of vaginal delivery. By means of the same equipment, surveillance of the cardiac activity of the neonate can be continued during its transport to the Intensive Care Unit and continuously maintained in nursery throughout routine care, feeding, medication, etc. Information obtained during this critical peri-natal period, may be of value to the pediatrician in the prognostication of impending respiratory distress and give an early indication of the need for special supportive measures.

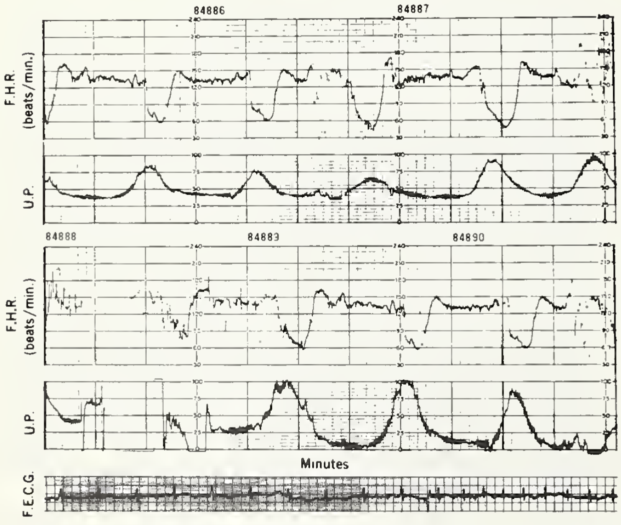

Figure 7
Tracings of telemetered fetal heart rate recorded during cesarean section. Upper tracing was obtained during transit to OR. Lower tracing was recorded during operation and delivery of vertex.

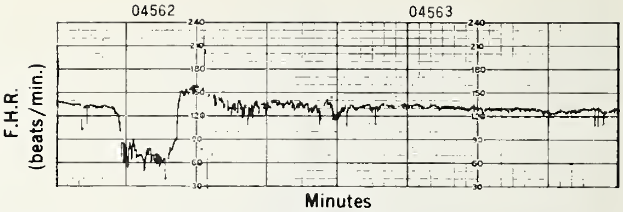

Figure 8
Tracing of f.h.r. showing response to $0_2$ administration after episode of hypotension.

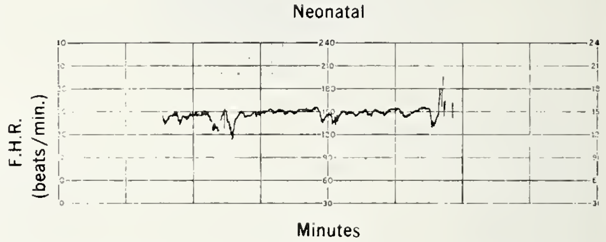

Figure 9
Tracing of heart activity of a premature infant transmitted from a crib in the I.C.U.

## Conclusions

1. A system of telemetry of the cardiac activity of the fetus and neonate during the peri-natal period is described.
2. A newly designed transmitter of small size for clinical application has been developed.
3. Tracings of telemetered heart rate patterns and changes in intrauterine pressure recorded in a variety of clinical settings are presented.

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# Important Advances in Clinical Medicine

## Epitomes of Progress—Internal Medicine

### Characteristics of Gonococci Which Disseminate in the Blood

Gonococci infecting the genitalia, pharynx or rectum may invade the blood to produce a variety of syndromes collectively called disseminated gonococcal infection (DGI). The most common syndrome of DGI, arthritis-dermatitis, results from the initial bacteremia and is characterized by fever and chills, typical skin lesions, and arthralgias or transient arthritis of the knees, wrists, hands or ankles. Infection of a large weight-bearing joint secondary to bacteremia (septic joint) may present as a typical, culture-positive, purulent arthritis with minimal systemic symptoms and negative blood cultures. Metastatic infection of the heart (endocarditis or pericarditis) or the meninges may present with findings typical of these diseases.

Three recently described characteristics of DGI isolates help to explain important features of the disease:

1. They are slow-growing and nutritionally fastidious requiring several growth factors not needed by most local isolates. This may explain the high incidence of asymptomatic local infections and the difficulty in growing them from the blood.

2. Despite increasing resistance to penicillins among other strains, DGI isolates remain extremely sensitive. For this reason, relatively short, low-dose penicillin regimens (for example, 3.5 grams of ampicillin given orally plus 1 gram of probenecid followed by ampicillin 500 mg every six hours for seven days) are effective for the arthritis-dermatitis syndrome.

3. Finally, two observations suggest that complement-mediated lysis of gonococci protects against DGI. First, DGI isolates uniformly resist lysis by antibody and complement in normal human serum, whereas only about two thirds of local isolates are serum-resistant. Therefore, only those local strains that resist killing by serum can invade the blood. Second, rare patients, deficient in one of the terminal components of complement responsible for bacterial lysis ($C_6$ to $C_9$), suffer recurrent gonococcal or meningococcal bacteremias. Because in these patients opsonization of gonococci occurs normally through the early components of complement ($C_3$ and $C_5$) but does not kill them, these cases illustrate an important role of serum killing in preventing DGI.

The tendency for DGI to be associated with asymptomatic local infections and to respond to low doses of penicillin, therefore, can be attributed to unusual characteristics of invasive gonococci. Recurrent neisserial bacteremia should alert physicians to a genetic deficiency in terminal complement components. Immunization to improve killing of resistant gonococci in the blood is a promising approach to the prevention of DGI.

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### Clinically Applicable Radioimmunoassays of Parathyroid Hormone

Both intact 84-amino-acid biologically active parathyroid hormone (PTH 1-84) and biologically inactive carboxyl-terminal ("C") fragments of PTH 1-84 circulate in human blood. The "C" fragments are derived both from the parathyroid glands and from the peripheral metabolism of PTH 1-84. Their concentration in the peripheral blood is relatively higher than PTH 1-84 because they survive longer in the circulation.

Serum radioimmunoassays (RIA) of PTH using antisera that react well with circulating "C" fragments ("C" assays) distinguish normal from hyperparathyroid subjects better than assays that detect only PTH 1-84. RIA's using antisera that react only with intact PTH 1-84 ("I" assays) are better in showing step-up differences between peripheral serum immunoreactive PTH (iPTH) and iPTH in serum draining parathyroid tumors.

All generally available RIA's of PTH have been developed with nonhuman reagents. Likewise, their ability to detect intact (amino terminal) or carboxyl terminal PTH have been determined with fragments of bovine PTH. Such studies do not adequately characterize the specificity of assays for *human* PTH. Fragments of human PTH are not commercially available.

At present, the only (and probably the best) way to characterize RIA's to be used for diagnostic purposes in humans is to determine the species of iPTH circulating in human peripheral serum recognized by a given RIA. This can be done easily by measuring the iPTH in the effluent fractions of gel-filtered hyperparathyroid serum and this information should be available to the user. Therefore, assuming adequate sensitivity, RIA's which recognize both intact PTH 1-84 and the larger molecular weight carboxyl terminal fragments of PTH in hyperparathyroid serum are "C" assays and can be expected to provide excellent discrimination between normal subjects and patients with hyperparathyroidism. RIA's which recognize primarily intact PTH can be expected to give the greatest step-up differences between peripheral and parathyroid venous effluent serum obtained during parathyroid localization procedures.

Selecting an appropriate RIA of PTH for diagnostic application has become a difficult and somewhat exasperating chore for most physicians because of the exponential growth in the number of assays available and competition-induced claims of advantages of one assay over another. The simple criteria given in this epitome for selecting clinically applicable RIA's for PTH should be helpful in making objective choices.

Claude D. Arnaud, M.D.

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## Hepatotoxicity Caused by Acetaminophen or Salicylates

Acute acetaminophen overdosage may result in massive hepatic necrosis with encephalopathy and death. Toxicity is mediated by an oxidized metabolite of acetaminophen that depletes intracellular glutathione levels. Generally, single doses in excess of 15 grams are required, although severe liver damage has occurred with ingestion of 10 grams in the presence of alcohol or drugs that induce the microsomal enzymes. Therapeutic dosages consumed for several weeks may also cause hepatitis with elevation of the serum transamines, alkaline phosphatase and bilirubin; centrilobular necrosis may occur. As little as 3 grams a day may be hepatotoxic, although injury seems more common at levels of 5 to 8 grams per day. The inflammation and necrosis are reversible on cessation of the drug, and no cases of cirrhosis have been reported with either overdosage or chronic ingestion.

Unlike acetaminophen, acute salicylate intoxication does not result in hepatic necrosis. Chronic ingestion of salicylates, however, in patients with acute rheumatic fever, juvenile rheumatoid arthritis, systemic lupus erythematosus or Reiter syndrome may lead to elevation of hepatic enzymes. Toxicity is unusual at serum salicylate levels of less than 20 mg per dl, but in one series toxicity occurred in all patients with juvenile rheumatoid arthritis in whom levels were greater than 25 mg per dl. Liver biopsy studies show a mononuclear cell infiltrate of the portal triads with scattered cellular necrosis that occasionally is consistent with chronic active hepatitis. As with acetaminophen, the toxicity is reversible. Lower dosages can be reinstituted providing the hepatic enzymes and serum salicylate level are monitored closely.

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## Cimetidine in the Treatment of Peptic Ulcer Disease

A new class of compounds, termed the histamine type 2 or H-2 receptor antagonists, has been added to the ever-expanding list of drugs used in the treatment of acid peptic ulcer disease. Cimetidine, the only H-2 antagonist currently available in the United States, has undergone extensive basic research testing and clinical trials documenting its ability to profoundly decrease gastric acid secretion. Histamine receptors on the gastric parietal cell playing an important role in the stimulation of hydrochloric acid secretion through all modalities (cephalic phase by vagal innervation, stimulated by food and stimulated by gastrin) are not antagonized by the traditional antihistamines (called H-1 receptor antagonists) such as diphenhydramine (Benadryl®). The H-2 receptor antagonists, such as cimetidine, block to a major degree the acid output stimulated by all known gastric secretagogues.

Early H-2 receptor antagonists, particularly metiamide, were found in some clinical trials to be associated with neutropenia on rare occasions. However, no significant toxicity has been found with cimetidine use, although isolated reports of gynecomastia have appeared. Cimetidine cannot yet be recommended to pregnant or nursing women.

Cimetidine has been shown to be effective in healing duodenal ulcers. Gastric acid secretion and acid delivery to the duodenum are significantly reduced with cimetidine therapy and it is associated with an improved rate of ulcer healing. Studies are in progress assessing the efficacy of cimetidine therapy in gastritis and gastric ulceration, as well as the prophylactic usefulness of continuous long-term nocturnal cimetidine administration for acid peptic disease.

Cimetidine usage should be considered in patients with gastric acid hypersecretory states such as Zollinger-Ellison syndrome and systemic mastocytosis and in patients who cannot or will not take effective doses of antacids for duodenal ulcer disease. The oral dosage is one 300 mg tablet with each meal and an additional 300 mg at bedtime.A parenterally administered form is available for patients who cannot take orally given medication. The drug should be administered in these latter patients in a dosage of 300 mg (mixed with 100 ml of a 5 percent dextrose solution) every six hours. The drug should not be used for dyspepsia without documented duodenal ulceration and it should be used with caution in patients with routine duodenal ulcers. With this drug, as with all new drugs, practicing physicians must be alert to unusual, unreported manifestations of toxicity.

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## Pituitary Cushing Syndrome: New Options for Treatment

Hypercortisolism in two thirds of all cases in secondary to excessive secretion of adrenocorticotropic hormone (ACTH) by the pituitary gland (pituitary Cushing syndrome). The mainstay of treatment for more than three decades has been total bilateral adrenalectomy. This treatment has brought its own problems including a significant mortality rate, persistent or recurrent hypercortisolism due to hyperplastic remnant or ectopic adrenal tissue, postoperative pituitary tumors (Nelson syndrome) and, almost invariably, lifelong dependence upon replacement therapy with adrenocortical hormones. Recent therapeutic advances now offer promise of making total adrenalectomy obsolete over the next few years.

Pituitary radiation has been used with limited success as a primary treatment in adults, perhaps only 15 percent to 20 percent of cases being fully responsive to $^{60}$cobalt radiotherapy in doses of 4,000 to 5,000 rads. However, children appear to be considerably more radiosensitive than adults and, as recently reported, as many as 80 percent can be effectively treated with radiation alone. While the lag period for full benefit may be as long as 18 months in some cases, the procedure is essentially free of morbidity, no hormone replacement is required and pituitary function has remained intact after prolonged follow-up. Based upon these encouraging results, cobalt radiotherapy can be expected to become the preferred initial treatment for pituitary Cushing syndrome in patients under 20 years of age.

Clinical trials of selected drugs have not as yet produced an agent which can be considered as sole definitive treatment. Mitotane, an adrenocorticolytic drug, has proved to be a useful adjunct for short-term improvement of patients who are incompletely treated or who are awaiting the full effects of radiation. An entirely novel, recent approach has been the introduction of two agents believed to alter brain neurotransmitter regulation of pituitary ACTH. Both cyproheptadine, a serotonin antagonist, and bromocryptine, a dopamine agonist, can ameliorate clinical features and reduce cortisol production. Careful studies of cyproheptadine indicate that not all patients are responsive and, when therapy is effective, relapse promptly follows discontinuation of the drug. However, the minimal side effects and possibility of spontaneous remissions with more prolonged treatment make these agents attractive for continuing clinical evaluation.

The single most impressive advance in management of pituitary Cushing syndrome has come with refinements in surgical procedures to the pituitary gland, now emerging as the treatment of choice in adults. This is due, in part, to improvements in radiologic diagnosis, particularly tomography, which has enabled the detection of pituitary microadenomas in more than 50 percent of patients, compared with the 5 percent in whom diagnosis is possible using conventional x-ray studies of the skull. These small tumors can now be viewed directly and resected, leaving the rest of the pituitary intact, using microdissection techniques made possible by the coupling of transsphenoidal surgical procedures with newer surgical microscopes. Two recent reports confirm 90 to 95 percent remission rates following removal of microadenomas and, equally impressive, this has been achieved without operative mortality and in almost all cases without permanent pituitary failure. It is noteworthy that whereas surgical operation in one series was used only in patients in whom abnormalties were shown on radiographs, Wilson and his group successfully operated on 16 of 17 patients despite normal findings on tomograms in 40 percent of them. This has led the latter group and others to advocate surgical exploration of the sella for every patient with pituitary Cushing syndrome regardless of tomographic findings. Another decade of experience may be required to clearly establish that removal of such microadenomas can be done safely with prolonged remission of Cushing syndrome and preservation of normal pituitary function. However, the short-term results make it apparent that at least for the next decade pituitary surgical therapy has replaced total adrenalectomy as the primary treatment for adults with pituitary Cushing syndrome.

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## Anaerobic Infections and Metronidazole

With newer microbiological techniques, anaerobic infections are now recognized as a substantial hospital problem. These include particularly postsurgical, posttraumatic, female pelvic and pleuropulmonary infections; and anaerobes are a common component in abscess formation. In cases of sustained anaerobic bacteremia, mortality approaches 50 percent.

Currently available antibiotics against anaerobes have gaps in their spectrum of activity, most notably against Bacteroides species or major toxicity. Bacteroides species make up 10 percent of all bacteremias recognized in hospital.

Metronidazole has a broad spectrum of antimicrobial activity and its utility against amebic and trichomonal infections is well known. It also has rapid irreversible bactericidal action *in vitro* against anaerobes, including Bacteroides. In man, it penetrates well from the blood into body fluids and appears to concentrate selectively in abscesses. It does not appear to antagonize other antibiotics.

It has been shown effective in treatment of patients with anaerobic sepsis or endocarditis, meningitis and brain abscess, posthysterectomy and postpartum pelvic infections, lung abscess or empyema, including patients who failed to respond to other antibiotics. In these cases, bactericidal blood concentrations correlate with successful outcome. It has also been effective in prophylaxis in bowel surgical procedures, appendectomy and gynecologic surgical operations.

Its use in antianaerobe therapy has been considered experimental in the United States in the absence of licensing for this indication. It has been available for oral administration only, but is absorbed after rectal administration and an intravenously given preparation is under study, which would allow therapy of seriously ill patients.

Side effects are minimal and infrequent, and include gastrointestinal disturbances at high doses, transient leukopenia and sensory neuropathy, headache and vestibular symptoms. Mutagenesis has been shown in bacteria but is of uncertain relevance, particulary because certain intracellular conditions correlated with this effect in bacteria have not been shown in humans. Carcinogenicity occurs in some rodents, but this is of uncertain significance since the doses and duration used in these experiments bear no relation to that used in human therapy.

Studies here and abroad indicate that this agent, at present undergoing further trials and possibly available in the future for general use in antianaerobe therapy in the United States, represents a major therapeutic advance—particularly against Bacteroides.

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## Hepatitis B Immune Globulin in the Prevention of Hepatitis B

Hepatitis B is a common infection reaching epidemic proportions in some populations. Previously referred to as "serum hepatitis," hepatitis due to the B virus is now known to be transmitted not only by parenteral routes but also by close physical contact and exposure of mucus membranes to the virus. Hepatitis B is easily diagnosed by showing the presence in serum of hepatitis B surface antigen (HBsAg) or by a rising titer of antibody against the surface antigen (anti-HBs). Recently, a preparation of hepatitis B immune serum globulin (HBIG) has become available.

HBIG can cost more than $150 per injection and two doses, approximately 30 days apart, are recommended. For comparison, ordinary gamma globulin

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(immune serum globulin, ISG), which may contain appreciable titers of anti-HBs, costs less than $10.

HBIG is prepared from plasma in a manner similar to common ISG except that the donor source of plasma is high in titer of anti-HBs. Both preparations are safe, neither transmits hepatitis, and side effects from intramuscular administration are low. HBIG has been shown in several controlled trials to reduce the likelihood of clinical illness and seroconversion due to hepatitis B. One large study of needle puncture exposure reported a 1.4 percent incidence of clinical hepatitis and a 5.6 percent seroconversion (anti-HBs) in subjects given HBIG. This was in contrast to a 5.9 percent incidence of clinical hepatitis and a 20.7 percent seroconversion of subjects receiving immune serum globulin containing uncommonly *low* levels of anti-HBsAg.

The United States Public Health Service Advisory Committee on Immunization Practices recommends the use of HBIG for patients with a single exposure to blood containing hepatitis B virus. This contact can take several forms, including needle puncture, mucus membrane contact or open wound contamination. Other less well established indications for HBIG use include exposure to body fluids other than blood products (urine, saliva stool and the like), close physical contact with carriers of HBsAG, and constant environmental exposure such as occurs in hemodialysis units or custodial institutions for the mentally retarded.

The initial intramuscular dose of 0.05 to 0.07 ml per kg of body weight should be given as soon as possible after exposure (not more than 7 days) and is followed by a second injection 30 days later. Confirmation of the HBsAg positivity of the donor is mandatory and showing the absence of anti-HBs is desirable if testing will not unduly delay gamma globulin prophylaxis. Chronic contact such as occurs in spouses of chronic carriers is not a sufficient indication for HBIG administration. Detailed question of the circumstances surrounding the actual exposure is necessary since many patients overemphasize the significance of their exposure because of anxiety. When doubt arises regarding the exposure, routine ISG therapy can be used as an alternative to HBIG because most currently available preparations of ISG contain significant levels of anti-HBs and may prove to be as effective as the more costly preparation.

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## Medical Versus Surgical Treatment of Coronary Artery Disease

It is estimated that in 1977 myocardial revascularization operations were carried out in approximately 70,000 patients. Recent studies, however, have questioned the efficacy of coronary artery bypass procedures in prolonging life. The most noteworthy of these are the multicenter randomized study on unstable angina and the Veterans Administration cooperative study on chronic stable angina. The unstable angina study required the patients to have unstable or changing anginal systoms in association with electrocardiographic changes during pain. These patients had to have at least a 70 percent stenosis of one or more of the major coronary artery branches. At the end of 24 months there was no statistically significant difference between the mortality of the surgical (5 percent) versus the medical (6 percent) group. It was remarkable that a third of the medically treated patients crossed over to the surgical group because of lack of adequate control of symptoms with medication. It was significant that there were three times as many medically treated patients in the functional class 3 to 4 group as surgically treated patients. The hospital mortality was not significantly different between medical (3 percent) and surgical (5 percent) groups. The myocardial infarction rate on the initial hospital admission was higher in the surgical group (17 percent) than in the medically treated group (7 percent) and this was statistically significant.

The Veterans Administration study on chronic stable angina showed no significant increase in the survival of medically treated patients versus surgically treated patients with one-, two- or three-vessel coronary artery disease. The major objections to this study are a graft closure rate of 31 percent and a surgical mortality of 5.6 percent, which are considerably higher than those published by many other institutions during the same period (1972 through 1974). This study did show, however, that patients with left main coronary artery disease fared significantly better with surgical than medical therapy.

At present at most major institutions the early hospital mortality for saphenous vein bypass surgical operation is 1 percent to 2.5 percent and the graft patency rate is 85 percent to 90 percent at 3 to 12 months. It is likely, though not yet proved, that in these centers longevity might be enhanced in the surgically treated groups. Though only improved longevity for patients with left main stem coronary disease has been confirmed, the quality of life for surgically treated patients seems to be better because 70 percent of them will be totally relieved of angina whereas only 30 percent of medically treated patients will be completely relieved. This could be especially important in young active patients who might survive a large myocardial infarction but be limited by angina or reduced ventricular function.

Physicians should be keenly aware of the surgical results of the centers to which they refer patients. The continuing national multicenter studies will shed more light on this controversy.

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## Diagnosis of Sjögren Syndrome

Sjögren syndrome (SS) is the second most common (and perhaps least well-known) connective tissue disease. Its estimated prevalence may be as high as 1 in 200. Sjögren recognized the generalized nature of the disease and defined the characteristic triad of keratoconjunctivitis sicca (KCS), xerostomia and chronic arthritis. Studies from several centers over the last decade have indicated the systemic and autoimmune nature of the disease, and the possible relationship to malignant lymphoproliferation. The hallmark of the disease is lymphocytic infiltration which can involve lung, liver, kidneys and muscles. Rheumatoid factor, antinuclear factor and other autoantibodies occur frequently.

Labial salivary gland (LSG) biopsy study is a major advance in diagnosis, permitting histopathologic confirmation of destructive lymphocytic infiltration. Multiple aggregations of lymphocytes replacing and destroying the acinar tissue characterize the lesion. An aggregate of more than 50 lymphoid cells is called a focus. More than one focus per 4 sq mm of glandular tissue is characteristic of SS, whereas such focus scores (greater than one) are found in less than 1 percent of either living or autopsy controls of all ages.

Although several techniques (such as measurement of salivary flow rate, scintiscan and sialography) can be used to document objective salivary gland dysfunction, only the presence of the characteristic histopathology is specific for SS. LSG biopsy is also more sensitive and specific than ocular examinaion for KCS in establishing the diagnosis of SS. The biopsy specimen should be obtained when a patient is not receiving high or rapidly changing doses of prednisone or other lympholytic agents because these may alter the findings.

Two of the following three criteria are necessary to definitely diagnose the connective tissue disease first elucidated by Sjögren:

- Characteristic lymphocytic infiltrates demonstrable on salivary gland biopsy studies,
- Definite KCS and
- An associated extraglandular connective tissue or lymphoproliferative disorder.

In our series, only 25 percent of patients have rheumatoid arthritis. Another 15 percent have systemic lupus erythematosus, scleroderma or polymyositis. In nearly half of cases there are typical extraglandular connective tissue and lymphoproliferative features in the absence of criteria for another coexisting connective tissue disease.

Because SS appears to represent an immunologic attack on exocrine organs, we have proposed the term autoimmune exocrinopathy (AE) to describe the syndrome better. AE is easily confirmable by an LSG biopsy study. Its presence may help diagnose unexplained systemic abnormalities suggestive of a connective tissue disorder.

Only 50 percent of patients referred for SS actually have an autoimmune disease. Other frequent causes of oral and ocular dryness include local glandular disorders, anxiety-depression syndromes and parasympatholytic drugs.

SS is the only connective tissue disease associated with transplantation antigens HLA-B8 and HLA-Dw3 and with the precipitating antibodies Ha, SS-A and SS-B which react with nuclear antigens. These are unique precipitins which can distinguish SS from other connective tissue diseases.

SS appears, therefore, to be a unique connective tissue disease related to but genetically, serologically and histopathologically distinguishable from rheumatoid arthritis, systemic lupus erythematosus or other connective tissue diseases. These latter disorders need not be present and therefore should not be required for diagnosis. The characteristic histopathology of the disease is most easily shown by results of LSG biopsy studies and may precede the exocrine gland dysfunction described by Sjögren.

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## Antinuclear Antibody Testing

Although antinuclear antibody testing was discovered some years ago, it is only recently that this test has become widely available. Because both the techniques of carrying out the test and the methods of reporting it vary, accurate clinical application of this immunologic test can be somewhat difficult.

As with any laboratory test, there are a certain number of false positives. Two percent of young adults will be positive at low titers (usually speckled pattern trace to 1+ at 1:16) in the absence of clinical evidence of any disease process. The percentage of false positive antinuclear antibody (ANA) tests in normal subjects rises to approximately 6 to 8 percent in persons more than 60 years old. This may be due to gradual loss of immunologic control resulting in antibody formation against nuclear constituents of cells undergoing the natural breakdown process.

In an endeavor to avoid the trap of diagnosing systemic lupus erythematosus or other autoimmune disease simply on the basis of a positive ANA titer, several items can be reported: (1) the strength of positivity on a scale of 0 to 4+; (2) serial tube dilutions and (3) the staining pattern.

The strength is important since most of the above noted normal subjects presenting with a positive ANA titer will have a strength of only trace to 1+ in the lower tube dilutions (1:10, 1:20 or 1:16, depending on the laboratory method). These all become negative at the 1:40 or 1:64 range. Some laboratories report "ANA positive" or "ANA negative." If the specimen is tested only undiluted, the percentage of positives will be much higher even than the 2 to 8 percent noted above; therefore, it is essential to have results on a diluted specimen to avoid excess numbers of false positives.

The pattern of staining can also be useful. Four types of patterns are quite readily discernible especially when present in high concentration: rim or shaggy, homogeneous, speckled, and nucleolar. These patterns represent various groups of antibodies, some of which are known to have clinical significance. The rim pattern is often seen in active systemic lupus erythematosus, especially when there is kidney involvement. The homogeneous pattern, especially when strong and at high titer, often represents active systemic lupus erythematosus. The speckled pattern is more variable and it is here that the greatest numbers of false positives are found. When strong, this pattern can represent mixed connective tissue disease, in which case a test for antibodies to ribonucleoprotein (RNP) or Sm antigen can be done. If the RNP antibody titer is high and there are no Sm antibodies, mixed connective tissue disease can be diagnosed in the appropriate clinical setting. If RNP and Sm antibodies are present, systemic lupus is suspected. The speckled staining pattern will also often be positive in progressive systemic sclerosis. The rarest pattern is the nucleolar which can be present in progressive systemic sclerosis, Sjögren syndrome or rarely other autoimmune disease.

Testing for antinuclear antibodies has largely replaced the lupus erythematosus or LE cell test, because of its greater reliability and its greater range of antibody detection. Since the LE cell test only detects one antibody (deoxyribonucleoprotein), it is present in only 70 percent of cases of systemic lupus, whereas the ANA titer should be positive in nearly 100 percent of such patients. Since the LE cell test is somewhat more difficult to run accurately and to read, and since it requires repeating on two to three different specimens for even marginal reliability, it is being replaced by the ANA test.

When can clinicians appropriately order an ANA test? When the clinical suspicion for systemic lupus or other autoimmune disease is strong, ANA positively helps in confirming the diagnosis. (However, without strong clinical suspicion on the basis of careful history and physical examination, a positive ANA titer should *not* be construed to indicate a diagnosis of systemic lupus erythematosus.) The second use of the ANA test is in following the course of the disease process by noting the change in strength of testing and tube dilution, which can help confirm disease remission or exacerbation.

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# Ticarcillin

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### Clinical Use

Ticarcillin disodium (Ticar®) is a semisynthetic penicillin approved by the FDA for the treatment of bacterial septicemia, skin and soft-tissue infections, and respiratory tract infections due to susceptible organisms. Although the drug is active *in vitro* against many Gram-positive and Gram-negative bacteria, it is primarily employed for therapy of infections from Pseudomonas aeruginosa and indole-positive Proteus sp. *(P. vulgaris, P. rettgeri, P. morganii).* On occasions, it is a useful agent in the therapy of infection from *Enterobacter* sp. In addition, ticarcillin is often administered in combination with an aminoglycoside (e.g. gentamicin, tobramycin, or amikacin) in febrile granulocytopenic patients, or in any patients with suspected bacteremia from an intraabdominal source. Ticarcillin or carbenicillin is also often added to an aminoglycoside in the empiric therapy of overwhelming sepsis, since these penicillins usually provide antibiotic coverage against the organisms such as streptococci and anaerobes that often are "missed" by the aminoglycosides. In the treatment of pulmonary infections due to *Pseudomonas aeruginosa,* a combination of ticarcillin and tobramycin appears superior to that of carbenicillin and gentamicin,[1] but it is uncertain whether the improved results are related to the ticarcillin or to the tobramycin.

### Microbiologic Considerations

Similar to carbenicillin, ticarcillin has good microbiologic activity against *Escherichia coli, Proteus* sp., *Enterobacter* sp., *Hemophilus influenza, Neisseria* sp., *Salmonella* sp., non-penicillinase producing *Staphylococcus aureus,* streptococci and most anaerobic bacteria including *Bacteroides fragilis ss fragilis.* Although ticarcillin is about twice as active as carbenicillin *in vitro* against *Pseudomonas aeruginosa,*[2-6] those pseudomonas which are resistant to carbenicillin are also usually resistant to ticarcillin. Organisms are considered susceptible if the minimum inhibitory concentration (MIC) is ≤ 100 mcg/ml. Selected bacteria for which treatment with this drug may be indicated are listed in Table 1. Synergy between ticarcillin and various aminoglycosides against *Pseudomonas aeruginosa* and other Gram-negative bacilli has been demonstrated by *in vitro* as well as *in vivo* experiments.[8] [9] Synergism, however, is usually not observed with aminoglycoside-resistant bacteria or those bacteria with high level of resistance to ticarcillin.[8]

Table 1
PERCENTAGE OF STRAINS WITH MIC* ≤ 100 MCG/ML

| *Organism* | *Ticarcillin* | *Carbenicillin* | *Ref.* |
|---|---|---|---|
| Pseudomonas aeruginosa | 89-93 | 70-83 | 2-6 |
| Indole-positive Proteus (P. vulgaris, P. rettgeri, P. morganii) | 84 | 84 | 5 |
| Enterobacter sp. | 97 | 97 | 2,5 |
| Bacteroides fragilis/ ss fragilis | 100 | 100 | 5,7 |

*MIC = minimum inhibitory concentration

### Pharmacokinetics

The pharmacokinetics of ticarcillin is similar to carbenicillin. Pertinent normal pharmacokinetic data[10] for both drugs are summarized in Table 2. Since ticarcillin is primarily excreted in the urine, clearance of this drug is markedly decreased in the presence of renal impairment: in patients with severe renal failure (creatinine clearance < 10 ml/min.) its half-life (T½) is about 14.8 hours;[11] in patients with normal renal function its half-life is about 1.2 hours. The drug is effectively removed by hemodialysis but only minimally removed by peritoneal dialysis.[11] [12] Half-life during hemodialysis is 3.4 to 4.9 hours.[11] [12]

Tissue levels of ticarcillin have not been well studied. Cerebrospinal penetration is poor in the

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Table 2

| *Pharmacokinetic Parameter* | *Antibiotic*<br>*Ticarcillin* | <br>*Carbenicillin* |
|---|---|---|
| Peak level (mcg/ml (2g I.V. over 30 min.) | 172 | 177 |
| Half-life (min.) | 74 | 67 |
| Volume of distribution (liters) | 14.3 | 12.9 |
| Protein binding (%) | 65 | 50 |
| Urine excretion (% dose) | 86 | 99 |

absence of meningeal inflammation, but it approaches an average of 39% of serum level in patients with meningitis.[5] Pleural fluid, peritoneal and biliary levels are 22%, 34%, and 92% of serum levels, respectively.[5] [13]

### Adverse Reactions

Like other penicillins, ticarcillin can cause hypersensitivity reactions and gastrointestinal disturbances. Platelet function abnormality and hypokalemia can result both from ticarcillin as well as carbenicillin, especially when they are administered at high dosages (e.g. 300-500 mg/kg/day).[5] [10] Patients with salt restriction should be carefully evaluated since the sodium content is 107 mg/g of ticarcillin, [15] which is about the same as when equivalent amounts of carbenicillin are administered. (The amount of sodium in the average daily dose in the therapy of severe pseudomonas infections is 2.15g/18g ticarcillin as compared to 3.66g/30g carbenicillin.)

### Dosage

The usual adult dose is 200-300mg/kg/day intravenously in divided doses every 3-6 hours. The dosage for complicated urinary tract infections (UTI) is 150-200mg/kg/day in divided doses and 1gm q6h for uncomplicated UTI. Dosage for children and for patients with renal failure may be obtained from the manufacturer's product information.

### Cost

According to the October 1977 American Druggist Blue Book, the cost of ticarcillin to the pharmacist is about the same as carbenicillin. The current actual costs to hospitals are $0.77/g carbenicillin versus $5.99/3g ticarcillin. The costs to the hospital for the average dose of 18g ticarcillin per day and 30g carbenicillin per day are $35.94 and $23.10, respectively.

### Summary

Ticarcillin differs from carbenicillin more in degree than in kind. Except for somewhat greater microbiologic activity of ticarcillin against certain strains of Pseudomonas aeruginosa, these two antibiotics can be considered similar. It is only in the therapy of established infection from Pseudomonas aeruginosa that it may be possible to administer a somewhat lower (20 grams of ticarcillin versus 30 grams of carbenicillin) dosage of ticarcillin, which in turn results in a lower sodium load (about 50mEq) for the patient. Except for a patient with significant underlying renal or cardiac disease, there is no evidence that this difference in sodium load has any clinical relevance. Now that cost-containment has become an important issue in the evaluation of antibiotics, it must be emphasized that at the present moment on a gram for gram basis, ticarcillin is more expensive than carbenicillin in the hospital setting.

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# Medical Peer Review and the PSROs: Current Findings on Relative Cost and Efficiency

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**ABSTRACT—This article summarizes briefly the findings of $1.1 million evaluation study of PSROs, published in 11 volumes by the Office of Planning, Evaluation and Legislation, Health Services Administration, DHEW. The emphases of the evaluation were utilization control, cost-containment impacts and program costs. The evaluation was conducted at a time when the PSRO program was in an early stage of implementation and studies impact the PSRO program had achieved by the start of 1977.**

**In a hospital utilization study of a group of 18 of the oldest PSROs and a matched comparison group of 26 non-PSROs, there were no significant differences in utilization between the two groups.**

**The PSRO program is more expensive than its utilization review predecessors. The cost of nationwide implementation of the original utilization review (UR) regulations was estimated at $81.3 million for 1976, while nationwide implementation of the 1974 revised draft UR regulations in 1976 would have cost about $107.6 million.**

**The DHEW report cautioned the reader against reaching final conclusions about the program since the evaluation was conducted during the time the program was in the developmental stage. However, the data suggested that PSRO implementation alone, without other changes to the health care system, is not apt to cause significant changes in either hospital utilization rates or associated governmental expenditures.**

The first comprehensive evaluation of the PSRO program, carried out by the Office of Planning, Evaluation and Legislation, H.S.A., U.S. Public Health Service, has been completed and publicly released. The emphasis of the evaluation was on the costs of the program and its effects on hospital utilization.

The authors warned, at the report's formal release, that the findings should be treated cautiously because the number of PSROs in operation during the study period was limited. However, the data strongly suggested that future PSRO implementation, at least in the present program format, would not cause dramatic changes in either hospital utilization or associated government expenditures. On the contrary, "comparison areas" utilizing forms of utilization review other than PSRO were not significantly different from PSRO areas in their utilization data, after appropriate adjustments for demographic characteristics. The PSRO program, however, was found to be significantly more costly than other forms of utilization review.

The evaluation just completed was an outgrowth of some of the major responsibilities given the PSRO National Council by the PSRO law. According to section 1163, the Council was directed to determine "PSROs' effectiveness and comparative performance," arrange for evaluation studies, and report to Congress. Under the Council's guidance, HEW staff developed a detailed plan, published in September 1975, to evaluate the PSRO program. The OPEL selected the most timely components of this plan as the guidelines of their work.

The entire OPEL evaluation, published in eleven volumes, covered history and background of the program, relatively thorough treatment of in-hospital utilization, a thorough treatment of program costs, case studies of PSRO management, and a very tentative treatment of program influence on quality processes. The emphases were not based primarily on relative importance of cost versus quality or of inpatient care versus ambulatory or long-term care, but on the current availability of data on different

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program aspects. The following discussion summarizes the four major utilization and cost studies.

### The Utilization Studies

The major empirical study of the entire evaluation was the analysis of Medicare utilization data compiled expressly for the evaluation from the enormous data base of the Social Security Administration. The Medicare Analysis investigated the effects of the PSRO program on hospital days of care per 1000 enrollees, hospital admissions per 1000 enrollees, and average length of stay. Eighteen active PSRO areas were compared to twenty-six matched nonactive PSRO areas. The matching procedure was quite elaborate, and utilized all known techniques for eliminating potential bias in the findings due to matching procedures. An active PSRO was defined as any PSRO area which achieved review binding for the purposes of claims payment of at least 50% of its Medicare discharges by January 1976. All areas meeting this definition were included in the analysis, with the exception of two which had a history of pre-PSRO concurrent review of Medicare hospitalizations and four which had no appropriate comparison areas.

The utilization data were statistically adjusted in a manner which had a net effect of removing from the raw utilization data all competing explanations for any observed changes in utilization. Adjustments were made for:

- pre-PSRO utilization levels
- population density
- percent of families with less than $5000 income
- hospital beds per 100,000 population
- weighted PSRO-wide hospital occupancy rates
- prior Medicaid concurrent review.

In overview, two types of utilization analyses were performed: aggregated and disaggregated. In the aggregated analysis the actual PSROs as a group were compared to the group of matched comparison areas after utilizing the adjustments detailed above. The aggregate analysis provided a stronger basis for statistical inference, in that competing explanations for changes were controlled for. In the disaggregated analysis, each individual PSRO was individually compared with its unique matched comparison area(s). The disaggregated analysis was useful in determining whether some PSROs seemed unusually effective in comparison with their own matched non-PSRO areas. The main purpose of the disaggregated analysis was to aid program managers in identifying PSRO operational techniques which seemed successful and could be spread to other areas as they were implemented.

In the aggregate, no statistically significant overall PSRO effect was found on average length of stay, days of care per 1000 enrollees, or admissions per 1000 enrollees.

In a subanalysis of the aggregate analysis, the interaction of hospital bed availability and PSRO impact was examined. That is, the possibility was examined that, although PSROs in general had no effect, they might have an effect when bed availability was either unusually high or unusually low. In fact, the data did demonstrate that those active PSROs with a *higher* number of beds per 1000 were more likely to show a reduction in utilization under PSRO review. The most likely explanation for this outcome is that an area with more beds is more likely to have hospital episodes of marginal necessity, while an area with a bed shortage probably had already decreased utilization to a reasonable level from sheer necessity, by a formal or informal triage process.

The disaggregated analysis, comparing each PSRO with its own matched comparison area(s), identified those PSRO areas which appeared to be reducing hospital utilization relative to their own matched comparisons. The analysis also identified those PSROs which appeared to be *increasing* utilization relative to their own matched comparisons. About 40% (7 out of 18) active PSROs studies were found to have *lower* (favorable) actual rates than would be expected if there were no PSRO effect. About 60% (11 out of 18) active PSROs studied had either *no* systematic variation of the actual rates from the expected rates, or had actual rates *higher* than expected. In other words, these 11 PSROs were either doing no better than their comparison areas, or were actually doing worse. When combined, these overall findings are not significantly different from chance expectation, and the most reasonable inference, statistically, was that PSROs have *no* effect on utilization.

It would have been extremely desirable to study these PSROs longitudinally, to test the hypothesis that performance changes with experience, because many speculative statements have been made to this effect. Since a number of longitudinal measures on the same PSRO were not available, a cross-sectional analysis of the group using each PSRO's "age" in months was made. The analysis indicated in a tentative way that experience may improve performance. A longitudinal study is in the planning stages.

It should be noted that any interpretation of this data rests on the fact that the PSRO was used as the unit of analysis, and that the treatment under investigation was the implementation of PSRO-type review using the PSRO management structure. While the results in that specific context are clear, it is less clear what they imply about the concurrent review process in general, apart from the PSRO organizational structure. If the matched comparison areas had had no forms of concurrent review, then the study results could have been interpreted to indicate that concurrent review is no more effective than retrospective review. This unqualified conclusion cannot be drawn, however, because the comparison areas actually had mixtures of concurrent and retrospective review of varying nature and intensity. In some of the very large hospitals in nonPSRO areas which were visited by the researchers, there were concurrent review programs equal in scope and intensity to PSRO review. This was, however, an atypical situation.

In a second component of the OPEL evaluation, a data base of 1.19 million hospital abstracts from 92 PSRO hospitals and 46 comparison hospitals was analyzed. These regions were substantially non-overlapping with the first utilization study's PSROs. Severity of case mix was examined using a staging methodology for 23 specific diagnoses. The staging methodology estimates illness severity from discharge diagnoses and other clinical information in terms of the natural progression of untreated illness. For example, simple appendicitis represents Stage I, while appendicitis with perforation and localized peritonitis is Stage II. The hospital abstract data analysis indicated that the following may be attributed to PSRO: slightly higher levels of Medicaid patient illness severity on admission, slight relative declines in average length of stay for Medicare patients, and slight relative declines in the percent of long stays for both Medicare and Medicaid patients. These same trends were also seen in the non-PSRO hospitals, but were of even smaller magnitude.

The relationship of decreased utilization to appropriateness of care was an issue which the OPEL evaluation was not able to address. There was an implicit assumption in the reporting of data that all decreased utilization occurred at no expense to the patient's health. That is to say, it was assumed that the decrease in utilization does not represent failure to prescribe or deliver necessary care. To date there is no generally accepted quantitative measurement of inappropriate utilization. Furthermore, it seems doubtful that a measurement methodology should be seriously attempted in view of the fact that there is no general agreement on detailed standards of care for each and every diagnosis. The authors freely admit that studies which automatically assume that lower utilization always has positive value to society are rather simplistic in conceptualization.

### The Major Cost Studies

Cost analysis represented a major component of the evaluation. Because of a lack of uniform accounting cost centers related to utilization review components, all cost data were constructed from onsite, structured interviews and inspection of accounting records. Hospitals, Medicare intermediaries, Medicaid state agencies, and PSROs were visited.

Four major cost activities were undertaken to determine:

1. Costs of Medicare Intermediary UR-related activities;
2. Costs of Medicaid State Agency UR-related activities;
3. Costs of delegated and nondelegated hospital review; and
4. PSRO administrative costs.

Cost estimates were developed to:

- Estimate selected unit costs;
- Construct a series of national cost estimates;
- Compare PSRO review costs with certain alternative forms of review (i.e., "Old UR" defined as the original UR regulations for hospitals, and "New UR" defined as the revised utilization regulation of November 1974);
- Determine the extent to which pre-PSRO review costs would be offset by the existence of PSRO review; and
- Provide a basis for cost-benefit analysis.

A summary of the major cost findings is listed below:

1. Unit costs: The estimated total costs of PSRO-delegated review (including MCE studies, review committee time, and administration) was computed at $11.20 (plus or minus 77¢ at 90% level) per discharge with estimated cost of donated physician time included. Estimated nondelegated concurrent review hospital costs per discharge were $8.99. The average PSRO level administrative costs per discharge were $7.11. Therefore, estimated total unit costs were $18.31 for delegated and $16.10 for nondelegated PSRO review.
2. National PSRO cost estimates: The estimated costs of a fully implemented program of 100% review, such as existed in 1976, were $268.5 million for federal beneficiaries and $689.9 million if all acute care hospital inpatients were included under PSRO review. These figures are based on review of 100% of patients. As a hypothetical example, if review had been focused on a 20% sample of discharges, costs would have been $184 million for 1976.
3. Comparison to "Old" and "New" UR costs: One concept which the study utilized was that of *incremental* costs. These costs were defined as the difference between the costs of a nationally implemented PSRO program (and associated review costs) and all governmental costs for review which would have been incurred in the absence of a PSRO program. These costs could be determined two ways, given the two following assumptions about alternatives: 1) Continued implementation of the original (pre-PSRO) utilization review regulations for hospitals;

2) implementation of the November 1974 revised utilization review regulations. Assuming the continuance of the original regulations, the PSRO incremental costs for a 100% review program were estimated at \$187.2 million. The incremental cost estimate with respect to the revised UR regulation implementation was \$161 million for 100% review.

4. Post-PSRO review cost offsets: Cost offsets were defined as the extent to which pre-PSRO Medicare intermediary, Medicaid state agency, and state survey agency UR-related costs would be discontinued with the introduction of PSRO review. However, from field data gathered, experience to date suggests that the PSRO program is not offsetting UR-related expenditures in Medicare intermediaries and Medicaid state agencies to any significant extent. The degree to which intermediaries and agencies should monitor PSROs is still a hotly debated topic.
5. Cost-Benefit Analysis: The original intent of the evaluation was to estimate an aggregate cost-benefit ratio for the 18 active PSRO areas contained in the Medicare Utilization Rate Analysis. This purpose was frustrated because the Medicare analysis ultimately did not generate any aggregate PSRO-associated rate reductions (benefits). Given this finding, two approaches were taken. First, an aggregate break-even analysis was conducted; secondly, individual cost-benefit ratios were calculated for those PSROs that were associated with relative declines in Medicare utilization rates.

The break-even concept, as applied in the study, indicated the number of days "saved" (reduced days of care per 1,000) required to cover or "pay back" the incremental costs associated with PSRO review. No attempt was made to value changes in quality, changes in product mix, or relocation of care to more appropriate sites, nor were long-range reductions in spending (such as some reductions in the supply of hospital beds) considered.

Incremental costs were estimated from the hospital cost data gathered during the evaluation and were defined as the sum of PSRO administrative costs for operation, the cost of amortizing start-up expenses over a ten-year period at 8%, and the excess of PSRO hospital CR costs over the costs of hospital UR for 1976 that were associated with Medicare review.

In aggregate, it was determined that if a 100% review PSRO program could achieve and maintain reductions in utilization rates on the order of 1.6% to 2.05%, the program would pay for itself. (For 20% focused review, the range would be 0.65% to 0.83%.) While current aggregate utilization rate impacts appeared to be below these levels, six of the seven PSROs that were associated with ralative utilization reductions did have benefit: cost ratios greater than one.

### Other Findings

The evaluation primarily addressed the effects of PSRO on utilization control, and dollars spent for medical care and reviews. There may have been other aspects of the program that were no less real but were more difficult to quantify. For example:

- Medical care evaluation studies, as carried out by PSROs and their delegated hospitals, appear to be potentially effective in identifying and correcting clinical and administrative deficiencies in care, but the frequency of the required reaudits is not adequate to date.
- Participation in PSRO activities, such as criteria development, medical care evaluation, and profile analysis, is considered to have an educational effect for physicians with respect to consciousness of the system consequences (cost, utilization, quality) of clinical practice.
- Similarly, these PSRO activities may improve the quality of care by requiring physicians to meet and deliberate on optimum clinical procedures, often requiring them to re-examine the assumptions underlying the way they practice medicine.
- Courses in medical care appraisal, no doubt stimulated by the existence of PSROs, are beginning to be offered in some medical schools and schools of public health, thereby markedly increasing the number of physicians who will consider the systemwide implications of their personal medical practice in the future.
- Many observers think that the presence of PSROs has pressured physicians to improve their documentation of care. The exposure of these records to systematic peer review has increased the ability of the medical staff to judge the quality of the work performed by its members.
- The existence of PSRO administrative structures and information systems has, in several instances, facilitated the implementation of other changes in the health care system. Professional Standards Review Organizations are usually better equipped than previous physician organizations to influence and assist such bodies as health systems agencies, planning agencies, and cost commissions.

**End Note**

For a more lengthy and detailed summary of the PSRO Evaluation, see A. Dobson, J. Greer, et. al., "PSROs" Their Current Status and Their Impact to Date," *Inquiry*, the Blue Cross Association, Chicago, Illinois, Volume XV, No. 2, June 1978, pp. 113-128, also, *PSRO: An Initial Evaluation of the Professional Standards Review Organization, Volume 1: Executive Summary;* U.S. Dept. of Health, Education, and Welfare, Public Health Service, Health Services Administration, Office of Planning, Evaluation and Legislation; Pub. No. 77-12; February 1978; 155 pages. (Distributed by the National Technical Information Service, *Springfield, Virginia* 22161. Order Number PB 278154/AS.)

# Informed Consent

## ELLEN WERTHEIMER

When I decided to enroll in "Law and Medicine: Informed Consent," a seminar taught by Jay Katz, M.D., at the Yale Law School, I wondered how such an apparently narrow topic could take an entire term to expound. I soon discovered both the breadth of the topic and the fact that it gives rise to more questions than it answers. Informed consent doctrine touches virtually all aspects of physician-patient relations and involves a third party in medical decision-making—the courts. Few if any of its aspects are free from difficulty.

Informed consent doctrine—generally interpreted as the requirement that a doctor give a patient all information having an impact on the patient's choice of treatment—sounds deceptively and seductively simple. With his class, Dr. Katz probes behind this doctrine and unveils at least three presuppositions upon which it rests: (1) that a coherent and definable body of facts exists for each decision which, if communicated to the patient, would fully inform him, (2) that patient competence or ability to make a decision and express it can be ascertained, and (3) that the medical and the legal professions know what kind of decision they seek to have the patient make.* Medical uncertainty precludes the truth of the first; individual diversity and the human capacity for self-deception make the second invalid; and intra-professional doubts forestall reliance on the third.

Dr. Katz, a professor at the law school and a psychoanalyst, begins his seminar by demythologizing medical certainty. Included in the reading materials for the course are medical journal articles which, as their authors argue over the treatment of choice for breast cancer, epitomize medical uncertainty. Disagreement over the most effective treatment for breast cancer introduces the students to the complexities of medical decision-making, and provides a medical example to which the course returns when confronting other problems of informed consent. In the articles, Doctors Crile, Anglem and others hurl theory and conflicting (though apparently equally scientific) statistics at each other in attempts to prove themselves correct. At the end of the argument, the student may only be certain that there is no medical certainty on which to rely in formulating standards of informed consent.

The fact of medical uncertainty in itself suggests that there can be no definitive answer to the question of what to tell the patient in order fully to inform him. The pat answer to this is that the doctor should inform the patient of all alternative treatments and possible repercussions and then let the patient decide. This circular response solves nothing. No standards exist stating how broadly accepted a treatment must be before its level of acceptance leads to the conclusion that it is so reasonable an alternative that a patient must be informed about it. The medical profession may disagree violently on what the viable alternatives are and, of these, which is the most effective. An unorthodox doctor may not believe in the validity of a broadly accepted remedy. Or a doctor may feel that a new treatment, as yet unaccepted by a substantial proportion of his profession, is the most effective. Does this qualify as an alternative? A patient may conceivably receive too much information and be encouraged to accept a relatively untested (experimental) treatment if the doctor is enthusiastic enough.

Not only is there disagreement within the medical profession, but also the doctor and the patient may differ on remedies. The doctor will probably wish to administer the remedy he considers the most effective, but the patient may have other priorities. Doctors tend to be dedicated to longevity; the patient may not be if, for example, the price of maximum longevity is

*There is, of course, a fourth presupposition: that the definition of informed consent given above sets forth what the doctrine really is. As the students discover through close readings of the cases, this is by no means clear. However, this problem will not be discussed here.

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severe mutilation or losing a breast. The doctor may thus be afraid to inform the patient of the existence of an alternative which, though less effective medically, comports better with the patient's goals. If the doctor feels that he can convince the patient of the validity of the treatment he wishes to administer, he will not hesitate to inform the patient of all conceivable alternatives. If he feels that the patient's priorities would interfere with the patient's making the decision which the doctor regards as correct, then (intentionally or not) his presentation of the treatments is bound to be biased. Ironically, the patient who is perceived as being the most likely to follow his doctor's advice (who trusts his doctor the most, and who is probably the least likely to involve his doctor in litigation) will also receive the fullest and least biased briefing.

From here, the course moves to an analysis of the courts' attempts to formulate a workable doctrine of informed consent. Forced by litigants, courts must decide not only who should make the decisions in medical contexts, but also on what basis decisions should be made. A doctor may, of course, seek to persuade a patient to accept one treatment over another on the basis of the doctor's scientific choice, but the doctor should also present alternative treatments to the patient—the choice in the end belongs to the patient. Courts face the virtually insuperable problem of ensuring that this principle is put into action. It may be humanly impossible for a doctor to tell a patient all alternatives in an objective, unbiased manner. (It is doubtful that either Dr. Crile or Dr. Anglem could present his opponent's view objectively.) Such a requirement would be unenforceable, to say nothing of the fact that it leads back to the original problem of ascertaining what the alternatives are.

It is likewise unworkable to demand that a doctor tell a patient of all important and relevant ("material") complications of a course of action and to base liability on an apparent failure to do so. The medical profession may not agree on what the possible complications are. Even if the medical profession were to agree on this, it may not agree when it comes to determining which are important. The percentage of likelihood of occurrence of complications would seem to be one way of assessing materiality—at least at first glance. However, one must first determine what percentage constitutes materiality, and then the percentage of likelihood of each possible consequence. The former is virtually impossible to establish, since a risk that is material where elective surgery is involved may not be as important where the issue is life or death. The latter is, of course, subject to the same medical uncertainty that caused the trouble in the first place. Courts are continually confronted with conflicting testimony from different doctors. When two thoughtful doctors differ, it hardly seems fair to hold one liable for failure to inform when he competently believed that a risk was not material on the basis of evidence from the other, who may believe that it was. Courts are at an after-the-fact disadvantage: it is easier to decide that a patient should have been informed of a given risk after that risk has materialized.

The second major presumption of informed consent doctrine mentioned at the start of this article is that patient competence or ability to arrive at a decision and express it can be ascertained. A patient may communicate his decision to the doctor; the doctor and court must decide whether to implement it. Hesitation in doing so may emanate from a patient's apparent irrationality, his age, his ignorance, or his physical condition at the time the decision is required.

On this issue, the course turns to a film strip on the case of Mr. G, a young man disastrously burned in an accident in which his father was killed. Mr. G wants the doctors to stop treating him and to allow him to die, both because he is in agony and because he cannot envision life as a cripple. The film strip shows a coherent individual who seems to be rationally propounding what he feels is a sensible solution to his problems. The class reacted to the doctors in the strip with anger at their forcing Mr. G to live against his will.

The question confronting the doctors, however, is not that simple. After a year, during which Mr. G constantly insisted that he wished to die, the doctors decided to implement his expressed wishes and cease treatment. At that point, Mr. G withdrew his objections to being treated. His insistence on death had resulted in part from the doctors' opposition. More importantly, he had also learned that he could bear the pain and the circumscribed world to which he would return. (He is now a law student.)

This case highlights problems in communication between doctor and patient; such communication involves more than speech. Mr. G spoke clearly, coherently, and sanely, and gave understandable reasons for his desires. This did not necessarily mean that his expressed wishes tallied with what he "really" wanted; he may have had other hidden reasons for wishing to die, reasons which, with understanding, might have lost their force. The problem lies in answering the implicit query: how can one tell what a patient really wants? It is clear that what he says, no matter how apparently sane (or insane), is not always a reliable indicator. Mr. G's words may represent what he wants, or they may be an expression of dismay at the changed life to which he merely needs time to adjust, or they may be a call for help in dealing with feelings which subconsciously motivate him to seek death. He may want to die at the time he voices his decision, but, if forced to live, may adjust successfully in a way he never would have thought he could. Does the doctor act in accordance with what the patient really wants by allowing him to die or by forcing him to live?

The compromise position—to require Mr. G to live for a time period to think it over, on the assumption that he is not in fit shape to decide soon after his accident—creates its own problems; one must determine both the length of time to be allotted and the genuineness of the decision at its end. To allow a waiting period merely postpones the decision on whether to follow the patient's instructions, but does not change the terms of the choice. As Mr. G's case shows, the length of time over which a patient maintains his desire to die does not prove its genuineness.

Courts and doctors have both sought to resolve the problem of deciding whether and when to obey a patient's expressed wishes with conceptions of competence and incompetence. These concepts come into play when a patient refuses much-needed treatment; when a patient is so terrified by his disease that his judgment is clouded; when a patient is a minor whose wishes (if he can express them) may not match his guardians'; when a patient is old and no one is certain how senile; when a patient is unable to cope with society or is clearly unusual (whether or not he has been committed); or when a patient's decision is motivated by a religious or other belief system dictating a decision with which most persons would not agree. (This last situation includes, for example, the problem represented by Jehovah's Witnesses, whose wishes have the cast of respectability organization gives them. But what about the person who is a firm believer in a religion of which he is the sole adherent? How many members must a belief system have in order to receive credibility?)

A decision made by someone considered incompetent may be ignored. Competence/incompetence standards, however, do nothing to resolve the problems of whether or not to implement the patient's decision. An individual who can speak clearly, and rationally justify his decision, may not really want to die, while an individual who might appear to be incompetent may genuinely wish to do so. Should a patient have to speak in language that passes some sort of competency test? And, if he does, does the fact that he is able to do so prove anything about the decision voiced? How unusual may a decision be before it becomes incompetent? Do incompetence and unusualness directly correspond?

Dr. Katz does not allow the class to assume that any easy boundary line exists between the competent and the incompetent—or, in fact, that any boundary line exists at all. For decision-making purposes, there may be no such thing as incompetence. An "incompetent" individual may live within a consistent value system that makes perfect sense to him; the fact that it is incomprehensible to everyone else does not speak to the genuineness of desires that arise from it. The energy expended in examining whether the individual is competent or not might be better spent in determining whether the individual is as unambivalent as he sounds.

The third presumption behind informed consent mentioned above is that medicine and the law know what kind of decision they want to encourage. The patient might decide on scientific grounds or on the basis of weighing scientific with other factors. These factors include the patient's feelings about certain kinds of disease, about certain kinds of surgery, about risks, about cost, and the like. Individuals will weigh different factors differently, and a scientific decision—which to the doctor involved usually means following the doctor's advice—may not be the best from the point of view of the patient. Since the doctor may be unwilling to aid in the making of a decision which he believes is medically incorrect, and may feel that informing a patient of a less effective alternative may lead to that result, the existence of such factors may consciously and unconsciously affect the information a doctor is willing to provide. Likewise, courts may be unwilling to implement as absolute the right of a patient to make a decision based on an individual set of criteria, particularly if those criteria lead to a decision the court is reluctant to support. Since standards of competence are vague and allow considerable discretion to the courts, the finding of competence or incompetence may depend on how advisable or sensible the court feels the patient's choice is. This is the same perception which may have dictated the action the doctor took or did not take prior to the case coming to court.

I hasten to add that doctor and court may both be acting in good faith in taking the decision away from a patient they regard as incapable of making a "correct" decision. But the belief that a patient is incompetent may too easily be tautological: courts and doctors often treat the patient's decision as the evidence of incompetence. A decision may thus be regarded as inherently incompetent, making a finding of incompetence depend not on the patient, but rather on what the court or doctor thinks of the choice and on how it accords with their conceptions of the sane or usual. A finding of incompetence all too easily becomes a value judgment on the decision itself.

Reading materials for the course, compiled by Dr. Katz, consist of approximately one thousand pages of articles (medical, legal, and lay), case opinions, legislation, and philosophy. Specific topics, centered around the study of doctor-patient relations, include: laetrile, placebos, death and dying, professionalism, autonomy, and paternalism, to name a few. The materials provide experience with the basic problems, existing answers, existing and potential conflicts, and the information needed as background to raising questions.

The primary goal of the course is one of inquiry.

Dr. Katz, confronting his students with their own acceptance of informed consent mythology, encourages them to ferret out and challenge the assumptions behind various formulations of the doctrine for intrinsic validity, practicability, and desirability. Alternative conceptions of what informed consent doctrine should encompass and what roles it should play in doctor-patient interactions are developed and dissected. The course raises the definitive questions which themselves may be the answers.

As the course progressed the extent to which medicine and the law differ in their approaches to problems of informed consent emerged. The law is concerned with predictability of result and the preservation of individual rights in general. A court must consider the implications for future uses of its reasons for reaching a given result in a particular case. Since each decision acts as precedent, a court cannot decide a case solely on its own merits. Law requires a determinate set of principles leading to a consistent set of results. To some extent, the individual case must defer to these goals.

Medicine, on the other hand, involves a private decision-making process—each decision may be made with reference solely to the specific individual and facts involved. Medicine is not a certain science; each decision is idiosyncratic. Except for effectiveness considerations, a doctor is not concerned with the impact the choice in a given case may have on future cases, but rather with the impact of the choice on the particular patient before him.

One of the most bothersome problems in formulating a workable doctrine of informed consent is that the medical and legal professions often seem to be working against rather than with each other. Doctors regard court-established standards as intrusions, and courts fear that the power the doctor wields will prevent patient choice. But despite differences between the professions—and legal principles and medical uncertainty are intolerant of each other—law and medicine suffer equally from a lack of cooperative effort. Without constructive medical participation, the guidelines set by courts cannot adequately take medical realities into account. This exacerbates conflict: doctors find themselves trying to follow impractical and ambiguous rules or ignoring them and facing liability; courts find themselves trying to decide cases on the basis of unworkable standards and hence using other unpredictable criteria, thus being forced into untenable positions and unfair results.

The most fundamental problems in formulating a workable doctrine of informed consent are shared. Law and medicine are both torn between dedication to individual autonomy and the desire to protect the individual from himself, between respect for privacy and the desire to help, between general principles and individual cases. The study of informed consent doctrine entails challenging and bringing into conflict some of the most fundamental postulates of our society. These conflicts must be faced and dealt with before the task of defining informed consent doctrine can begin.

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# National Health Care Planning

## A Year by Year Factsheet

**1946**

Passage of original Hill-Burton Act. Legislation provided Federal funds for hospital construction, but also established a survey analysis process by which states would use available Federal funds to fill unmet needs in hospital construction.

**1964**

Amendment of the Hill-Burton Act, setting up the legislative authority to fund regional or areawide health planning agencies. These were sometimes called "318 agencies," for their original legislative authority (not the funding authority) was contained in section 318 of the Public Health Service Act. This was the first instance of significant Federal financial involvement in local or regional health planning.

**1965**

Passage of the Heart Disease, Cancer and Stroke Amendments of 1965 (P.L. 89-239), which added Title IX to the Public Health Service Act. This Title became the genesis of the Regional Medical Program (R.M.P). Provided for regional "cooperative arrangements" among health care institutions, medical schools, and research institutions for the diagnosis and treatment of heart disease, cancer and strokes.

**1966**

Passage of the Comprehensive Health Planning and Public Health Services Amendments of 1966 (P.L. 89-749). Authorized a two year program of Federal support for comprehensive health planning. Three types of grants were authorized: (1) Formula grants to states for statewide health planning. ("a" agencies); (2) Project grants to public or private non-profit agencies to pay up to 3/4 of the cost of operating areawide comprehensive health planning agencies ("b" agencies), and (3) Project grants for the training of health planners.

**1967**

Passage of the Partnership for Health Amendments of 1967 (P.L. 90-174). The modifications required the state CHP agencies (the "a" agencies) to assist health facilities in developing programs for capital expenditures, required the states to bear a quarter of the cost of their planning efforts in FY 70, and required the representation of local governments on areawide CHP agencies ("b" agencies).

**1968**

RMP legislation extended for two years, by P.L. 90-574.

**1970**

Passage of the Medical Facilities Construction and Modernization Amendments to the original CHP legislation. Required areawide ("b") agencies to open up appropriate representation for hospitals, other facilities, physicians, and the public on governing boards. First legislative requirement regarding the make-up of Boards.

**1970**

P.H.S. amendments of 1970 (P.L. 91-515). This Act further spelled out the membership requirements of the Boards of the areawide agencies, and called for the establishment of a health planning council for each areawide agency. These amendments also called for:

(1) The RMPs and Federal health programs (including Veterans Administration hospitals) in a State be represented on the State Health planning council; State CHP agencies could receive project grants under the areawide health planning authority (section 314(b)) to provide planning assistance in areas where the resources or capabilities did not exist to support an areawide agency;

(2) Areawide agencies assist health care facilities in their areas in developing a program of capital expenditures for replacement, modernization, and expansion, consistent with the overall State medical facilities plan;

(3) Applications for grants for health services development be referred to the appropriate areawide CHP agency for review and comment and that the services to be provided by the applicant to be in accordance with plans developed by the State agency;

(4) A National Advisory Council on Comprehen-

sive Health Planning Programs be established to advise the Secretary on policy matters relating to health planning; and

(5) The State CHP agencies give increased emphasis to planning for home health care and environmental health.

These amendments also extended the CHP authorities for three additional years, through 1973, with increased authorizations.

**1970**

P.L. 91-515 extended RMP authority for an additional three years. Coverage was broadened to include kidney diseases, but retained its categorical focus. New emphasis was placed on primary care, regionalization of health care resources, new construction authority, and better health manpower utilization, especially in underserved areas. Significantly, a requirement was also added that obliged RMPs to submit their grant proposals for review and comment to their areawide CHPs.

**1972**

Passage of Social Security Amendments of 1972 (P.L. 92-603)—added section 1122 of the Social Security Act. It provided that health care facilities and HMOs would not be reimbursed by Medicare, Medicaid, or the maternal and child health programs for depreciation, interest or return on equity capital relating to capital expenditures that were determined by designated State CHP agencies to be inconsistent with standards, criteria or plans developed by the State agencies. This important provision related expenditures under Medicare and Medicaid to State health planning for the first time by assuring in effect, and Medicare and Medicaid would not support the construction of unneeded health care facilities, as determined by State CHP agencies. It was clear in the legislative history of this provision that States should use recommendations from areawide agencies to assist them in the implementation of this provision.

The important concept embodied in this legislation, that health financing should be closely related to health planning, has subsequently been reflected in almost all major proposals for national health insurance through a series of devices intended to assure that national health insurance does not pay for costly services which the planning process determines are unneeded.

**1973**

Passage of the Health Program Extension Act, extending RMP authority for one additional year.

**1974**

Passage of National Health Planning Act (P.L. 93-641). This is considered one of the most significant pieces of health care legislation ever enacted. The Act establishes ten National Health Priorities for consideration in developing and operating Federal, State and area health planning and resources development programs: These ten priorities are:

(1) Provision of primary care services for medically underserved populations, especially in rural or economically depressed areas.

(2) Development of multi-institutional systems for coordination or consolidation of institutional health services, including obstetric, pediatric, emergency, intensive, and coronary care and radiation therapy services.

(3) Development of medical group practices, health maintenance organizations, and other organized systems for the provision of health care.

(4) Training and increased utilization of physician assistants, especially nurse clinicians.

(5) Development of multi-institutional arrangements for the sharing of support services necessary to all health service institutions.

(6) Promotion of activities to achieve needed improvements in the quality of health services, including needs identified by the review activities of Professional Standards Review Organizations (P.S.R.O.'s).

(7) Development by health service institutions of the capacity to provide various levels of care (including intensive care, acute general care, and extended care) on a geographically integrated basis.

(8) Promotion of activities for the prevention of disease, including studies of nutritional and environmental factors affecting health and the provision of preventive health care services.

(9) Adoption of uniform cost accounting, simplified reimbursement, and utilization reporting systems and improved management procedures for health service institutions.

(10) Development of effective methods of educating the general public concerning proper personal health care and methods for effective use of available health services.

The Act also establishes a 15 member National Council on Health Planning and Development to advise the Secretary of Health, Education and Welfare.

Still more specifically, and of considerable direct importance to Region VII Comprehensive Health Planning, are the provisions for establishing geographical units known as Health Service Areas and the subsequent designation of organizations called Health Systems Agencies.

Health Service Areas are designated by the Governors of the States throughout the country.

**1975**

No budget request for RMP program. White House recommends its phase-out.

# *Month in Washington*

Stringent controls and across-the-board budget cuts will be the order of the day for the coming 96th Congress. President Carter has announced that his anti-inflation program will be the top domestic priority and such sentiment appears to be wide-spread among returning members.

The Administration's initial thrust in the health area will be its demand for the hospital cost containment program that was blocked in the last Congress. In addition, it is expected that the President's chief selling point for his brand of national health insurance (NHI) will be its alleged ability to hold down inflation in the health care sector.

In an important policy address before the National Press Club, Joseph A. Califano, Secretary of the Health, Education and Welfare Department, warned that if liberals want federal social programs to survive, they must concentrate on better management of those programs rather than on their expansion.

"It was the challenge of Liberalism in the Sixties to enact long-delayed and much-needed social programs," Califano said. "It is the challenge for Liberalism in the Seventies to manage these programs well."

"As we come to the close of the Seventies, the challenge for the American Liberal is the challenge of austerity," Califano said.

There is a management revolution underway in Washington, the HEW Secretary said, an "effort to make compassionate programs work efficiently."

He said it is essential for Liberals to recognize that times have changed, that "the self-confidence of the Sixties has been replaced by a mood of caution, wariness, and skepticism."

Califano didn't say where the economic ax will fall at HEW except to note some long-standing targets such as impacted federal aid for schools and the hospital cost containment plan. Of the latter, he said House Speaker Thomas O'Neill (D-MASS.) has promised early House action next year. "We will drive that legislation through next year," he said.

* * * *

While Secretary Califano and the Administration appear to be unalterably opposed to private sector voluntary efforts to reduce inflation and adamantly in favor of mandatory wage and price guidelines for the health sector only—via hospital cost containment and NHI—other views are being expressed in Washington.

A Washington symposium of national business and health leaders, during a briefing of how voluntary cost containment is working in hospitals and among physicians, heard AMA Executive Vice-President James H. Sammons, M.D., urge the federal government not to interfere and "play games with the nation's health."

Speaking at a think-tank session in Washington, D.C., sponsored by Arthur D. Little, Inc., Dr. Sammons said to some extent the problems currently facing the health care industry have made providers "victims of our own success." He pointed to the highest quality of care in the world in this country and the rapid explosion of medical technology since World War II.

Health care is going to be expensive and the question must be asked whether benefits can be expanded without costing more money, said the AMA official. Much talk has been bruited about the percentage of health in relation to the Gross National Product.

"Is 8.6 percent too much or too little? What is an intelligent yardstick?"

He suggested that medical people make medical decisions, such as who qualifies for renal dialysis. "Let's be sure we know what we're doing when we do it."

Dr. Sammons said the Voluntary Effort is succeeding on several fronts and that prospects for the future look good and "America's physicians are playing a leading role in our society's quest to keep medical costs within reason."

He noted "the dimensions . . . and the dangers . . . of certain governmental proposals to slap arbitrary and ill-considered cost ceilings on our medical system."

"Most people, including most people in government, realize that when it comes to fashioning enlightened and enduring answers to complex problems the private way is by far the better way."

Paul W. Earle, Executive Director of the Voluntary Effort, said VE is a unique national coalition formed by physicians and hospitals to voluntarily contain health care costs.

It marks the "first time we have done it in the industry on a coalition basis." Often the groups "fight among themselves but we are now joining together on major tasks."

Earle said this is the "only industry that has responded with a massive, nationwide effort to President Carter's call for voluntary restraint—ironic

*(continued on page 41)*

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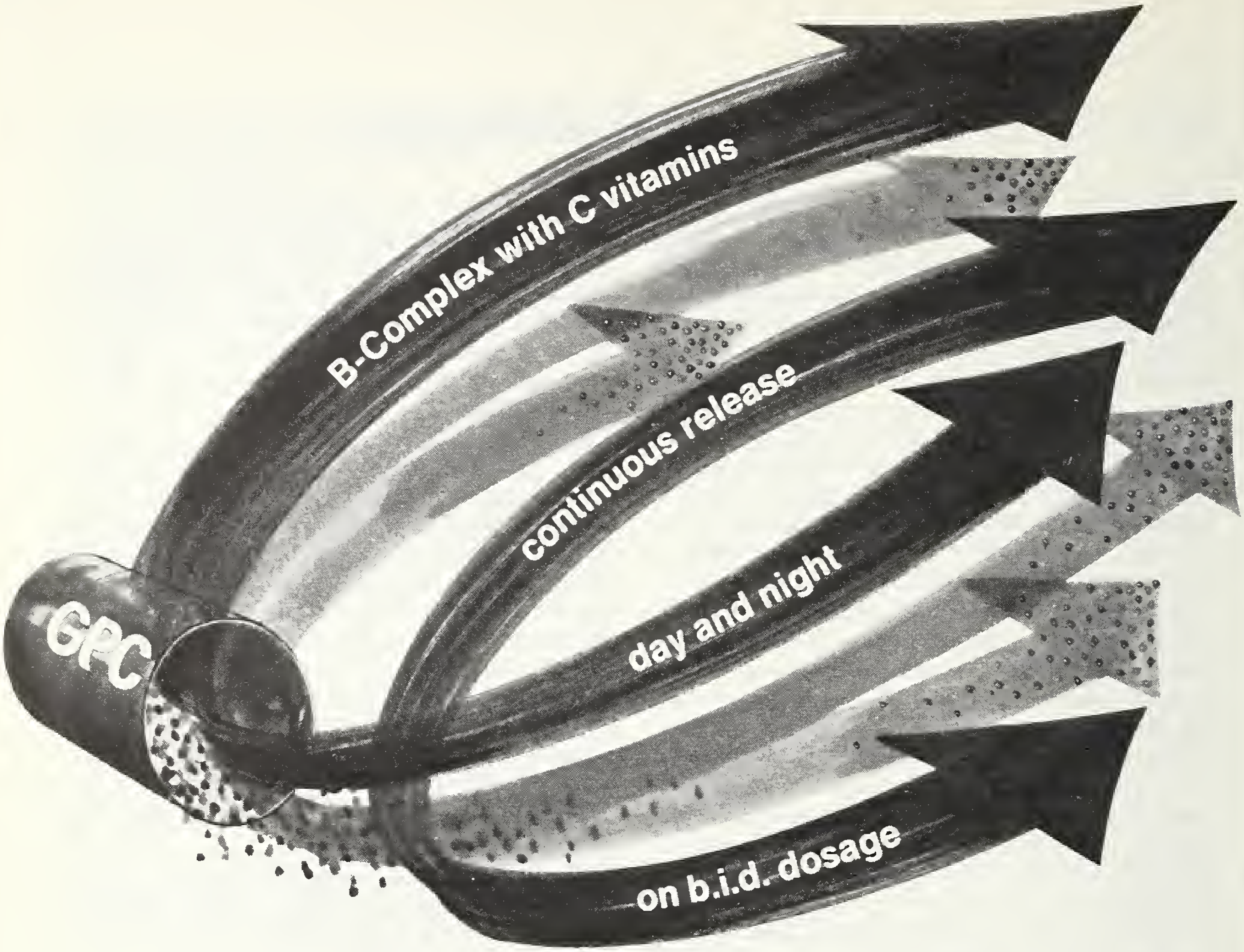
*Prepared by the Washington, D.C.*
*Office of the American Medical Association*



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inasmuch as the Administration has called for voluntary restraint but is pushing for wage and price controls for hospitals."

The National Steering Committee is led by the AMA, American Hospital Association and the Federation of American Hospitals.

"And we are getting results anyway you measure it, Earle said, noting the following "rate of increase" statistics:

| | |
|---|---|
| 1976 | 19.1% |
| 1977 | 15.6% |
| 1st half of 1978 | 12.8% |

"Industry is doing the job, demonstrating its responsibility and we don't need the federal government telling us what to do," he asserted.

Dr. Sammons noted that the rate of increase in hospital expenditures through the first seven months of 1978 was 12.8 percent, well below the 1977 rate of 15.6 percent and the lowest since 1974 when federal wage and price controls were ended.

Dr. Sammons estimated that Voluntary Effort has saved $900 million in hospital costs in the fiscal year ending in September, 1978. He further estimated that it will save $44 billion by the end of 1983.

* * * *

Government health planners are considering a "productivity standards" system to examine the efficiency of physicians and hospitals.

HEW Secretary Califano said such standards could cut unnecessary surgery, make better use of expensive machinery and shorten hospital stays.

"I recognize that we must proceed with great care in attempting to set standards regarding health care productivity," he said. Any such move should not infringe on physicians' relationships with patients, he said. The National Health Planning Council was asked to begin "careful consideration of the issues raised by productivity standards."

Califano did not go into detail about minimum productivity standards in a speech at the annual meeting of the Institute of Medicine, a branch of the National Academy of Sciences.

"A concern with productivity presumes a strong doctor-patient relationship characterized by human caring," he said, noting that physicians, economists, professional standards groups, hospitals, nursing homes and other medical facilities would contribute to the set of standards.

With the "moonshot age" of complex medical technology and refined special skills have come the problems of unnecessary medical procedures and a proliferation of facilities which are under-utilized, said Califano.

He noted that in 1975 there were more than three hospital workers per patient in this country while the ratio in West Germany was one-to-one and two-to-one in Great Britain.

According to the Secretary, nurse practitioners and physician assistants "could handle more than 50 percent of patient visits for primary care problems more economically—at least in certain settings—than doctors.

* * * *

A broad-based coalition of health and environmental groups aimed at disease prevention was proposed by Rep. Paul Rogers (D-FLA.) who declared he's convinced the coalition will perform a valuable role in informing the public.

The tentatively-titled National Coalition for Disease Prevention and Environmental Health held its first strategy and organizational meeting in Washington, D.C. with 30 groups forming an organizing committee. Rogers told representatives of these and other groups that he intended to play an active role in supporting the Coalition, but he apparently will not head it. Rogers, retiring this year as head of the House Commerce Health Subcommittee, said he would announce his future private role shortly, but would serve the Coalition "for free."

Some 140 national groups have expressed an interest in joining the group, according to Rogers. The educational and information exchange functions of the Coalition will be critical, he said. The organized groups would survey food, the safety of consumer products, the purity of air and water, the safety of the work place, and strive for a "less stressful society."

* * * *

The Health Maintenance Organization (HMO) program, one of the few major health bills of the last congressional session to secure enactment, has been signed into law by President Carter.

The measure, a prime goal of the Administration, provides a three-year extension, with certain amendments to the HMO proposals.

The bill authorizes $31 million, $65 million, and $68 million for the next three fiscal years.

The maximum amount of an initial development grant that can be made was increased from $1 million to $2 million beginning in fiscal year 1980.

The government can make loans and loan guarantees for the acquisition or construction of ambulatory health care facilities and for the acquisition of equipment. Loan guarantees to private HMOs can only be for projects that will serve medically underserved populations. The loans made or guaranteed for an ambulatory health care facility cannot be more than $2.5 million.

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# Congress and Carter's Hospital Cap

WARD SINCLAIR

There was a time not so long ago when, to be blunt, it wouldn't have mattered much if newcomers like Marty Russo or Dave Stockman were members of Congress.

They would have come to Washington, scrambled to stay in office, patiently learned the system, listened respectfully to their elders, accrued seniority. Eventually good things would have come to them, as though by divine confirmation: committee or subcommittee chairmanships, clout enough to cow a bureaucrat, even the power to influence national policy.

It is not that way anymore, which is one of the reasons President Carter's proposal to curb skyrocketing hospital costs never found its way through the thicket of the 95th Congress.

Russo and Stockman have spent a total of six years in Congress—not much in an institution known as a haven for septuagenarians. But when the administration's bill was beaten in the House Commerce Committee last summer, it was they—and not powerful committee chairmen or leaders like Speaker Thomas P. (Tip) O'Neill, Jr. (D-Mass.)—who played key roles.

Russo, a two-term Democrat from Chicago's southwest suburbs, broke with his party and Carter—who before he was president had helped elect him in 1974—to cast the vote that killed the administration cost-control plan.

Stockman, a freshman Republican from Michigan, developed amendments that effectively gutted the majority president's plan and persuaded his colleagues to approve them.

A number of factors, including administration miscalculation and industry lobbying, came together to undermine the hospital bill. But one of the more obvious factors was Congress itself, the way it functions these days and the attitudes that guide it.

Russo and Stockman, as neophytes with a voice, are beneficiaries of some of the major changes that occurred in Congress during the past decade—changes that dramatically affect the way business is done.

House and Senate changes have spread more power to younger members, giving many of them (including Russo) subcommittee chairmanships. Heavy turnover—more than half of the members have come here since 1972—keeps the committees changing rapidly.

Chairmen, fearful of ouster, no longer can run their committees as personal duchies, dictating members' votes. This was particularly true on the hospital bill.

Party loyalties are divided and younger members, feeling more independent, respond to their own instincts and special power bases at home. When the Commerce Committee defeated Carter's cost control bill, nine of the 22 votes against it were cast by Democrats. Six of the nine were first- or second-termers.

Reforms have created something approaching subcommittee government in Congress, and while these reforms have eliminated some overlapping jurisdictions, Carter's hospital bill had to face four subcommittees. Each had a chairman with a different idea.

On the Senate side, Edward M. Kennedy (D-Mass.) supported the Carter bill. Herman Talmadge (D-Ga.) thought Carter's bill was too sweeping. In the House, Rep. Dan Rostenkowski (D-Ill.) didn't like mandatory controls. Rep. Paul Rogers (D-Fla.) supported the controls, but he knew compromises would have to be made.

Each of the four subcommittees would get to take a crack at Carter's bill. And then each of the four parent committees would have its turn.

This meant more members would be able to tinker, that special interests would have more opportunities to work their will, that the administration's task of getting its bills passed would be infinitely harder.

A decade ago, for example, Carter's bill would have gone to one committee in the House and one in the Senate. Last year, it went to two committees in each

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WARD SINCLAIR, *Washington Post* Staff Writer. Contributing to this story were *Washington Post* Staff Writer Mary Russell and researcher Valarie Thomas. Reprinted with permission from "Administration's Bill Loses Out As Rules on Hill Have Changed," *The Washington Post*, Nov. 14, 1978.

chamber and subcommittees in each committee. That made eight major station stops.

The bill reached seven of the eight stations but at each of the stops it ran into peculiar problems of politics, power and personalities.

After the first stop, however, the administration had reason to be buoyed. Kennedy's health subcommittee moved quickly and produced a bill that in several respects was tougher than what Carter had proposed. By early August 1977, the full Human Resources Committee had approved the Kennedy bill. Joseph A. Califano, Jr., the secretary of health, education and welfare, cheered it as a "dramatic first step."

At the same time Carter's plan was in Kennedy's Senate subcommittee, it was under consideration by the House Commerce health subcommittee, chaired by Paul Rogers. Known around Capitol Hill as "Mr. Health," Rogers was one of the House's most skillful legislative craftsmen. But his subcommittee needed from May until October to complete its work on an amended version of the Carter plan, and Rogers found that the political air had changed.

"The independence of the members . . . you can't count on them in the 94th and 95th congresses," one of Rogers' aides commented. "Four years ago, Paul Rogers would work it out with subcommittee members. It became high unholy treason to amend a committee bill. But we didn't even have all of our members on this—we lost the us-against-the-world syndrome that Rogers is usually able to cultivate. It worked in the past, but it has become increasingly difficult."

By the time Rogers' subcommittee had acted, the health subcommittee of the Ways and Means Committee was preparing to move. Energy, taxes, Social Security and welfare revision, among other things, had taken much of the committee's time until then.

And by then, Rostenkowski, the subcommittee chairman, saw trouble ahead. He never much liked the idea of mandatory controls, but in any case, he wasn't going out of his way to do favors for Califano.

Califano earlier had refused to follow Rostenkowski's suggestions for a couple of high-level HEW appointments. The congressman was chafing over that and, while he denied it was a factor, it gave him one more good reason not to be keen about mandatory cost controls.

"We needed hospital cost-containment," he said, "but the attitude of my colleagues here gave me every indication that it wouldn't fly. It could not be passed."

Rostenkowski had another idea. He challenged the hospitals to voluntarily restrain their costs and came up with a bill that called for federal controls after two years if the voluntary effort failed.

Even with that moderate approach, he had problems in his subcommittee. The hospitals detested the trigger and were telling legislators about it. Rostenkowski's prestige—as deputy whip he ranks fourth in the House hierarchy—was suffering.

Alternately begging and threatening, he got two subcommittee votes he needed, but the scent of disaster was in the air.

By Rostenkowski's count, the bill could not make it through the conservative Ways and Means Committee. He and Rogers then took a new tack. They would move the bill to the full Commerce Committee, get it passed—they thought—and win leverage for votes in Ways and Means. Califano agreed to go along.

"Then it became do-or-die for the industry in the Commerce Committee and they smelled the sweet fragrance of victory and they went for it," Rostenkowski said.

The scene at Commerce was chaotic. Markup sessions dragged on for six weeks in June and July. Amendments came by the fistful. Hospital lobbyists intensified their calls on members.

Rogers and other Democrats pushed for a quick action but Rep. Harley Staggers (D-W.Va.), a benign chairman, let the committee move on its own course. He once adjourned the panel when delay-minded Republicans insisted on attending Flag Day ceremonies.

The opposition had every chance to stir the waters. One of the stirrers was David Stockman, a first-termer who, on his own, developed an array of statistics and data to show why he felt mandatory controls would not work.

Like many of the 95th Congress's newer members, Stockman knew which bells to ring to make the system work for him. He had been an aide to Rep. John B. Anderson (R-Ill.) and was director of the House Republican Conference before his election.

His idea was that cost controls on the hospitals was the wrong approach. Rather, he argued, a limit on the so-called third-party payments—from health insurers, that is— would push costs down.

"My real design was to offer amendments to dramatize and point out that that whole approach was defective. I wanted to allow it to sink of its own weight," he said.

Stockman's freedom of movement symbolized one of the big changes in congressional procedures. Another change—the larger, bright staffs behind the members—showed up at the same time.

A committee member working just as fervently on the other side was Rep. Andrew Maguire (D-N.J.), another second-termer with a Harvard Ph.D. in his background. Maguire, like many other members, had built himself a cadre of staff specialists who knew how to ask questions and get answers.

He had help on the hospital bill and other health measures from full-time assistants hired for their expertise and from no-cost fellows from the Robert Wood Johnson Foundation, which makes help available to members.

One thing that means is that their ideas become the congressman's, translated into debate or amendments.

Joe Onek, presidential assistant on hospital cost matters, noted the impact of the larger staffs and the expert fellows on loan to Maguire and other members.

He went to have lunch with Maguire one day and ended up in something akin to a seminar. Maguire took his experts along to lunch. "Members of Congress are no longer rubber stamps," Onek said. "Their staffs have more ability. Even when they agree with you, it slows things down."

If institutional change was slowing the process, the medical-hospital lobby had more elbow room for working its influence. Each day of committee delay gave the lobby one day more to work on the fence-straddlers.

Among the targets was Russo, who denied the lobbyists affected him but who, nonetheless, voted the way they wanted in his surprise reversal at the Commerce Committee last summer.

Russo's vote became a cause celebre, not so much because of his independence but because of the way he expressed it. He never told his old friend, Jimmy Carter, or Paul Rogers that he would bail out at the last minute. When he did, it left them in the helpless bind of having no time to convert anyone else.

The last time Russo told the president about his position, Carter had turned him around—collecting on the political debt from 1974, as it were, when Carter had campaigned for Russo. Carter pleaded and Russo changed his position on natural gas deregulation—allowing the president's plan to win by one vote in the committee.

But Russo didn't like the pressure. "On the hospital thing, I was in agony as to whether I should tell him or not. If I told him, he would have used everything at his disposal to change me around. That's why I wasn't interested in calling him and getting all that pressure," he said.

The hospital experience left Russo somewhat bewildered. Carter later was quoted in the Chicago papers as saying that Russo "betrayed" him. In a meeting with other congressmen, Carter pointed at Russo and told how, by one vote, an important bill had died.

And then Juanita Kreps, the secretary of commerce, canceled a seminar meeting with businessmen in Russo's district. Democratic campaign officials let it be known that Russo wouldn't be getting any financial help this year.

"The administration just doesn't know how to handle things," Russo said. "I would have made Marty Russo feel so bad he'd have been there with the administration the next time. If they're trying to punish me, they're giving me all the help in the world."

"They really don't understand the politics," he continued. "This is a very independent Congress—it doesn't vote the party line. The younger members—Democrats and Republicans—vote their district more and more. If the issue merits it, I support it."

There was no doubting that this was a different kind of Congress, but in a view of Andy Maguire, it wasn't administration ineptitude or the free-for-all spirit at the Commerce Committee that did it in. Plain and simple, he said, it was the power of the hospital lobby.

"Those negative votes were more a reflection of the concerted lobbying effort of those who were affected. They were here all the time, even though I was not with them. They just kept coming back," Maguire said.

That's how Califano saw it, as well—an uphill struggle against a lobby that only time and education could overcome. "The educational process is getting through," he said. "We'll be way ahead next year . . . . We just underestimated the extent to which we had scratched a big money tree."

The medical lobby's money for congressional campaigns was only a part of it. As Califano would learn, the money tree's roots of influence reached into nearly every community in the country. The tree would not be toppled with ease.

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The second Update Symposium will be held Tuesday, February 14, at the UConn Health Center, Farmington. The topic is "Hodgkins Lymphoma and Myeloma." The new series is sponsored by the Connecticut State Medical Society, the Connecticut Oncology Association, the American Cancer Society, Connecticut Division, and the Yale Comprehensive Center.

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# The Computer in Medicine: Friend or Foe

### ROBERT A. FISCHL, M.D.

In less than a generation the computer has advanced from an exotic, almost far-fetched concept to practical reality. The speed at which computer technology, usefulness and practicality are advancing is remarkable. Ten years ago a computer was a roomful of large cabinets packed with electronic devices. It was practical only for large organizations and major hospitals to own and use one. This year computers, the size of a large bread box are available and are being installed in doctors' offices. Projecting that rate of progress into the future, we may carry computers in our pockets or on our wrist another ten years hence.

Computers are being programmed for teaching, for interpreting specific medical investigations, including electrocardiograms, multiphasic screening tests, X-rays and scans. Already the computer is not just a calculator, but a thinking device.

The computer has entered a new phase, and so has medicine. Previously it was a tool, an aid, a calculating machine. Now it is capable of making decisions. No longer need its conclusions be interpreted by the doctor. The print-out of a computer *is* the decision. It can stand by itself. Granted, the computer makes errors, some due to the program, some to the information being fed in. They are becoming less frequent, certainly less ludicrous, as technology advances and instructions to the computer become more precise and operators become more sophisticated and knowledgeable.

In using computers as a tool it is necessary to guard against frivolous or promiscuous applications, lest valueless numbers beget an even greater mass of useless statistics.* This phenomenon has become known as G.I.G.O.—"garbage in - garbage out."

Perhaps we should begin to ask not only where is the computer going but in which direction will it take us. In dealing with the computer, medicine is in the position of the man who gets a puppy and finds that it grows and grows and grows. No longer does he have the dog on a leash. The dog now leads the man. This is no seeing-eye dog. This puppy has already grown to the size of an elephant and it is still growing.

We shall have to take care not to get trampled or crushed. It would be misleading to think that the computer, because it lacks an M.D. degree, is not capable of making decisions as well as a physician. What we learn painfully in medical school and subsequently, by repetition, intense application and hard work, can be fed into the computer in a fraction of the time. Moreover, it will be retained. So let's not be complacent. The M.D. degree won't protect us.

Rather than complain about the inroads of the computer, rather than fear its inevitable intrusion and advance into medical practice we should welcome it, use it wisely, and prepare to change ourselves and the practice of medicine in order to cope with the immense benefits, foreseen and unforeseen, the computer brings. We can't fight it, so we'd better join it—or, better still, have it join us.

In making decisions we cannot hope to compete. The computer uses logic. The physician uses a combination of logic and what has been called "intuition." What is intuition, after all, but the addition of small fragments of information which have not been verbalized or quantitated, but which together make up the deciding factor in triggering that "intuition?" I do not believe that intuition is a God-given gift. It is, after all, gained by experience and it uses our thinking capacity superimposed on logic, to a refined degree. Perhaps the intuitive thinking process is the trump card which we have over the computer, but unfortunately intuition is not infallible and it is certainly not reliable. So we must look elsewhere for those human qualities where we excel.

Our five senses, long neglected in the practice of medicine, will have to come to the fore. "The sixth sense" may even help, but first we must learn to harness it and make it reliable.

*Fischl, R.A. Tools of Research—And Its Aims, New York State Journal of Medicine: 69:1236-7; 1969.

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ROBERT A. FISCHL, M.D., Attending Surgeon, Plastic Surgery, Danbury Hospital, Danbury, CT and New Milford Hospital, New Milford, CT.

In considering those functions of the doctor that may possibly be taken over by computers we must look at those functions in light of computers' capabilities and shortcomings. A computer can calculate, reason, make choices. It can examine visual images by scanning, and it can count. What, then, can it not do? Thus far it is not possible for a computer to touch, to smell, to feel, or to respond with feelings, with sincerity. Computers do respond to questions, but thus far these responses have been purely mechanical and without human emotion. It would, therefore, seem that a psychiatrist could not easily be replaced at this time since much of his interaction with the patient is one of sensing emotion and controlled response. I say "at this time," because it is not inconceivable that a computer may be designed which can perform the functions of the psychiatrist, just as teachers can be replaced by electronic teaching machines. I can imagine a patient in need of psychotherapy, lying down beside a computer, or even sitting up at its keyboard, describing his dreams and emotions on that keyboard and receiving appropriate responses by a televised read-out or programmed recorded phrases and interpretations.

Now let us look at the intellectual functions, such as those performed by an internist. Diseases handled by the medical specialties are usually dealt with in the classic sequence of combining symptoms and signs to reach a diagnosis and then prescribing treatment.

It is already practical for a computer to be fed information, be fed the patient's symptoms and for it to respond with appropriate questions, to request clarification. The computer is then fed further information such as the signs found at an examination and the results of laboratory examinations. A diagnosis or differential diagnosis is the response and further investigations or examinations may be recommended. When a diagnosis has been reached, the computer can recommend therapy.

The only thing the computer is, so far, unable to do is look, listen, feel and smell.

In this possible future competition with computerized medical services, the surgical specialties are at a distinct advantage. Much of a surgeon's functions are performed with the hands and the eyes. Diagnoses are made in a similar way to medical diagnoses, but in the case of surgical conditions much more reliance has to be placed on feeling, i.e. palpation.

Scanning by an electronic sensor to determine heat output as in a thermogram, light output as in a television camera, and radio activity, such as a liver scan is a practical reality. The only thing that cannot be done mechanically is palpation. It is not beyond the bounds of possibility that a device can be manufactured which will "feel," as tonometers have been used for generations to measure the pressure in the eyeball, for instance. A "scanning tonometer" could be designed which will prod a patient in a predetermined pattern and print out a series of readings. This could give a map of the pressures or resistances in a given location, such as the abdomen, very similar in appearance to a barometric map. Of course, this concept has not taken into account the patient's reluctance to be prodded by a machine. But mechanized medicine has not stopped in the past because of such scruples. In determination of "tenderness" the patient could be asked to respond by pressing a button whenever that prodding causes pain. This could be printed out into a tracing of areas of tenderness.

We have seen, therefore, that the diagnostic functions of a surgeon are not inviolate from take-over by computerized techniques.

Let us examine whether it is possible for a computer to do the surgery? Surgery is a combination of cutting, pushing, sewing, seeing, feeling and thinking with a careful co-ordination of all these elements. Thus far computers have been used to cut along predetermined lines, as patterns for clothing and cutting out materials for manufacture into garments. This requires two-dimensional cutting. It is possible to imagine a knife which can be guided by a computer to cut in three dimensions, provided that these are predetermined. In this generation, it is not possible to imagine how a computer can guide a knife in response to program instructions, even for a simple operation, such as sebaceous cystectomy. For the computer to perform an appendectomy would require considerably more sophisticated interconnected responses. I should think that any operation would require more co-ordinated technology than it is possible to visualize at this time. Even repairing a wound is not within the capacity of a computerized sewing machine. It is easier to perform a wound closure than to describe it.

Therefore, it may be a relief to some surgeons to know that it will take longer to replace the surgical specialist than those whose expertise is contained within the intellect. Then those doctors who could perform well with their hands folded, who felt their speciality was superior to that of the "cutting doctors" may need to re-think what is is that makes them indispensable—what makes them superior to a computer—a thinking machine?

Mechanical tests should not be the main component of any examination. Our senses can be our biggest allies in guarding our patients from feeling we are impersonal towards them. The only thing a physician can do better than a machine is to look, to listen and to feel. We know that computers often make mistakes and they have difficulty deciding between various possible conclusions, but so do people. When I think about the future of medicine I am re-assured by the fact that we have hands and eyes and ears. We should use these more, because they are the only functioning parts we possess which are not easily replaced by a machine:

Hands to touch, to make contact, to feel and to perform delicate tasks, whether they are with a scope, a probe, a needle, or a knife. It will be a long time before anyone, even politicians, allow a machine to perform these tasks.

Eyes, not only to see what is in front of them, but to make visual contact for "rapport," to observe and to show emotion. The eye seeks out, it scrutinizes, it can look through a magnifying glass and it has expression. I think the eye is not only for looking. It can be looked at, also.

Ears to hear, or to choose not to hear. The ear can listen to the patient's story, his questions and his anxieties, and it can gain a great deal of information from the inflection of the voice, the manner in which it is told and the pauses. Even what is unsaid can have meaning. Then, too, the ear is an important adjunct instrument when used to notice the creaking of a joint, the patient's wheezing and much more, when applied to the stethoscope. Percussion of the chest also involves the ear, but I wonder whether this is still done, or whether it is useful. As a medical student I even learned to use percussion to determine the size of some organs, such as the heart and the liver. It was used to demonstrate whether there was motion of the diaphragm and we were taught "scratching auscultation" to size up the dimensions of a distended stomach. Has all this lost value now that these findings can be made by X-rays?

Performing these physical examinations on the patient gets you around from behind the desk, away from the chart-rack to the bedside; into proximity and into contact with the patient.

The nose, too, can be used to make some diagnoses: Ketosis, gas gangrene, and the recent consumption of alcohol, for instance.

At any rate, the use of any of these sense organs and the use of our hands is what makes us better than computers. Computers can, after all, be programmed with the decision-making processes designed by our most brilliant colleagues and be kept up-to-date by frequent modifications of the program. But, as of this date, we are in a better position to supply the "input" of the things we have seen and the sounds we have heard when we *examined* the patient.

A machine may be devised to interpret the findings of what can be seen on an X-ray, but I doubt if a machine will ever be manufactured which can intelligently guide a needle into a blood vessel, a bronchoscope into the lung or a lumbar puncture needle to the proper spot. It will also be many years before a knife can be wielded, or stitches placed by machine, without the human hand and eye to guide it. It is, however, possible that surgical conditions may be treated more by medical means in the future, thus making surgeons less necessary—or less surgeons necessary.

So let us, as doctors, remember what we are good at, and practice along those lines. We can re-assure a patient better than the output of a computer. We can get at the root of his anxieties better than a "multiphasic screening" examination, and we can break bad news to him better than a "print-out" card.

We can truly render medical *care*, with all the meaning of that word. We can care for the patient, and we should make every effort to care *about* him, in such a way that he knows and appreciates that care.

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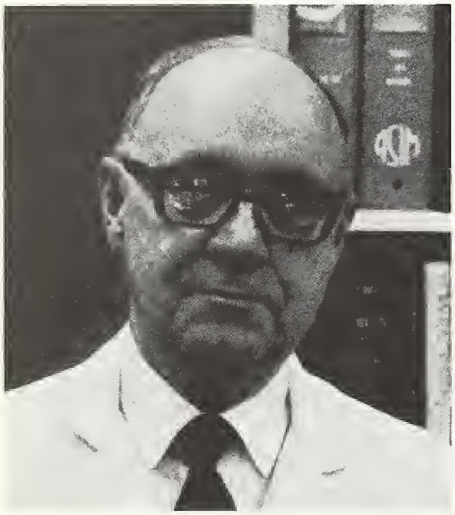
The saving of lives is not enough. The perfecting of lives should be the aim. Medicine must ally itself with those forces which make for the best access to the materials and opportunities which promote happiness and stimulate physical and moral perfection in men and women. Medicine, in the end, must be concerned for cultural values—the passion for wisdom, beauty, and justice. These are the real expressions of health.—James Peter Warbasse, "Three Voyages," in *The Doctor and the Public*, 1935.

“THE PHYSICIAN IS A DECISION MAKER, AND ALMOST EVERY DECISION HE MAKES COSTS OR SAVES MONEY.”

*—Dr. William Felts, Past President,*
*American Society of Internal Medicine*



More and more physicians today are beginning to realize the extent of the economic influence they have, and are finding ways of holding costs down.

A number of studies show that the more physicians *know* about costs, the more they try to *reduce* them.* And this reduction can be done without reducing the quality of care to the patient.

How are they doing this? As a start they have become thoroughly familiar with the costs they incur on behalf of their patients. They know how much an X-ray costs, how much their hospital charges for routine lab tests. They’re requesting copies of patients’ hospital bills. And asking their hospitals to print the charges for diagnostic tests right on the order sheet.

What else are physicians doing? Minimizing their patients’ hospital stays, whenever possible. Reevaluating routine admissions procedures. Questioning the real need of the diagnostic tests they order for their patients. Avoiding duplicate testing. Trying to discourage their patients’ demands for unnecessary medication, treatment or hospitalization. Compiling daily logs of their medical decisions and what they cost. And more.

More physicians today realize what a tough problem we’re all faced with. They know this is a challenge for medicine. And that physicians are in the best position to deal with and solve the problem.

**PATIENT CARE Magazine—Outlook 1977, “Face-Off: Cost Containment vs. Chaos,” January 1, 1977.*

*Lyle CB, et al. “Practice habits in a group of eight internists,” ANNALS OF INTERNAL MEDICINE 84 (May 1976), 594-601.*

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# The President's Page

## The Federal Government and Medical Ethics

Hard and unyielding as are the words of Judge Barnes' proposed order in the suit by the FTC against organized medicine, the real impact lies beyond them in their implications. For two years medical associations would be totally forbidden to interfere in any way with any solicitation or advertising by physicians or organizations with which physicians are associated, nor with any terms under which physicians sold their services and we would be proscribed from restraining in any way the development of or advertising by any prepaid health care plan.

If your analysis has not progressed beyond advertising and solicitation, you are missing two far more dangerous results of the decision. The lesser is that all medical societies—local, state, and national—would be required to alter their constitutions and bylaws to conform not to the wishes of their members but those of the FTC. To a physician like myself not expert in the law, this seems a real intrusion into the rights of voluntary, non-profit organizations. And if this weren't grave enough, the FTC—after two years of proscription of us from the various activities—proposes to generously allow us to promulgate guidelines for the ethics of advertising and solicitation but, and read this carefully, only after advance approval by the FTC. The arbiter of a profession's ethics would be an agency of the Federal Government and not those governed by those ethics. Orwell's 1984 has arrived six years too soon! To give you some idea of my feelings, allow me to tell you some of what I have learned about Administrative Law. Charges are made against us by a federal agency. We are then tried by that agency through an administrative law judge who, for all appearances, is in its employ and in this case who is said to have been a prosecutor for the same agency before his appointment as law judge. To add to my wonderment, I find that we may appeal to the agency that drew up the charges against us in the first place. But I had heard that we still could appeal to the federal court system. And then I found that the court review is generally limited to law, not fact. So it is possible that the appeal will have to be pressed to the Supreme Court itself. And I have it personally on the highest authority that the AMA intends to press as far and hard as it has to, to obtain redress.

I learned along the way that the majority of law made in this country is not made by courts nor legislatures but by governmental agencies, state and federal. On the federal level the agencies are supposed to be checked by the Congress which may strike down agency law. But apparently the torrent of such law overwhelms the Congress and it appears that the agencies are less well-checked and balanced than they should be.

The bureaucrats believe that unrestrained advertising will lower prices. Many of us believe that the marginal practitioners, the charlatans and the dishonest will certainly use the situation to the detriment of both the physical and financial health of the consumers. The sick are susceptible to the blandishments of the quick and easy cure, the guaranteed cure and the offering of hope in hopeless situations. All professions have conceived it as their duty to require their members to abjure misrepresentation of their services, talents and results because the consumer of professional services often purchases as much the intangibles of sympathy, concern and honesty as he does a product such as surgical procedure. If the government wants unrestrained solicitation for two years and then wants to control our ethics, perhaps we should consider the course of not promulgating these guidelines as long as they are really those of the FTC and not our own. If there is damage done I am not sure I want our profession to be any part of it.

By the time you read this, I will have urged the Council of the Connecticut State Medical Society to proceed forthwith with appeal to the courts for no one I have consulted really expects the Commission to reverse the judge in any major way. I cannot think of any better way to expend our resources than to try to preserve our professional freedom. It would be a sorry profession indeed that, without a fight, allowed its ethical standards to be imposed on it without the consent of the governed, without appeal and certainly without democratic process. If Hippocrates were alive, he would have to clear his Oath with the FTC in advance. There are many Connecticut physicians who for various reasons have opted not to support the AMA, who now should join together with the rest of us.

As I have said to you in earlier communications, we were left a fine tradition and wonderful ideals along with economic opportunities by those who preceded us. What will we leave to our professional descendants concerns me greatly. I do not think I make an excessive request when I ask for the support and help of all of you in the battle just beginning. The AMA will continue to bear by far the greatest burden and we much less. I am confident the members of our Society will not fail in their duty in the critical days ahead.

Jerome K. Freedman, M.D.
*President*

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# Reflections from the Dean's Office

## Democracy High and Low

ROBERT U. MASSEY, M.D.

At a recent conference of medical school deans, a regulator was lamenting the trials of his profession: "The problem," he declared, "is that everybody thinks he's unique, and regulators have to be able to treat everybody alike."

That indeed is the problem. Government and most managers, without intending it, look toward the working out of the consequences of the social equivalent of the second law of thermodynamics, when everything and everyone everywhere will be flattened and the same. That original and ultimate chaos was and will be the simplest to manage. It was only after the sixth day that the Creator had trouble with His material creation.

In reality, each of us, as well as each of our institutions, is unique, and the greater the effort to undo that uniqueness, the higher the cost, and vaster the power required of the regulator. Politicians, rulers, and managers are accumulators of power, most especially when their aspect is benign and they are bent upon good works. Power is then given to them; they more often receive than take away our liberties.

In its *Report on the Cost of Regulation*, the Hospital Association of New York State[1] has concluded that "25 percent of hospital costs are attributable to meeting government regulator requirements;" that would be about $20 billion nationally, if the cost of regulation elsewhere were as high as it is in New York State. That assumption is not justified except in a few highly regulated states, but even if the 25 percent of costs were only half as high nationally, hospital costs of regulation would be two or three times the amount spent for biomedical research and development. This does not count the costs of the regulating agencies themselves, nor the costs of regulating other elements of medical and dental care.

Some regulation is essential; in any society there must be rules, and rules must be enforced, and regulators must be prepared to do that. But costs also must be counted, and a profit and loss statement for each regulation ought to be drawn up, even though we would know that it would be full of biases and shaky assumptions. The New York study admits to that.

However, cost is not all, and to concentrate on the balance sheet alone is to apply the bookkeeper's standards to matters which ought to be considered against wholly different values. The regulator, whom I quoted earlier, said that the "average must be the standard." Institutions with costs above the average are to be brought down; presumably that process would go on *ad infinitum* until everything is brought to a common level of meanness. Regulators have neither the time nor the knowledge to go behind the regulation *in each instance* and to judge the matter against the ideal which society had in view when the rule or law was written. What began as a commendable effort to assure the highest quality of medical care must end by reducing all medical care to a level everlastingly declining below the mean.

There need be nothing conspiratorial about the imposition of regulations. The public interest and safety must be protected. Medical care costs as a percentage of all expenditures are becoming surprisingly large, and the market forces operating to hold them down are less effective than those of the used car market. If the market does not ration, something else must. It is a matter of internal or external control.

Early in this century Alfred North Whitehead wrote, "We are at the threshold of a democratic age, and it remains to be determined whether the equality of man is to be realised on a high level or a low level."[2]

High quality, efficiency, and the liberty to explore, to invent, and to change are not incompatible except in a highly regulated society, or democracy on a low level. There is indeed no other way than the regulator's way, unless the norm of society is adherence to high standards of intelligent self-discipline in the exercise of freedom and in the use of resources. I think that is what Whitehead meant by democracy on a high level.

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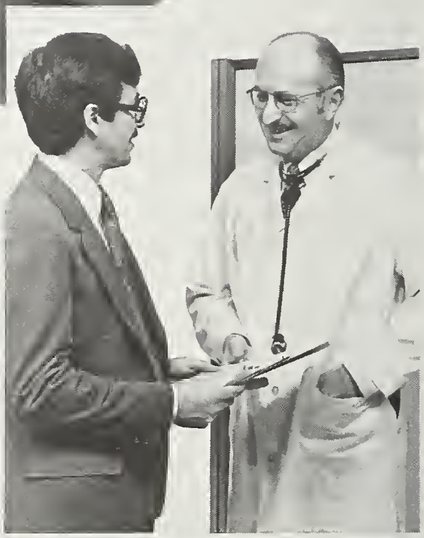

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# EDITORIALS

## Our Nervous Health Picture: Our Changing Society

Health delivery system: a phrase much used but often ill defined. Historically, when Americana was ripening in flavour about the turn of the century, the socio-economic unit was the town or township, the basic political concept of home rule was the town meeting and the health planning agency was the family doctor. This doctor's native intracranial computer could easily provide for the medical, surgical, obstetrical, pediatric, social, school health, public health, meat inspection and sports medicine needs of his entire village or town. Furthermore, local decisions were reached rapidly enough that the slow rate of dissemination by travel or communication had little impressment effect upon the surrounding community units. During these days the doctor with his assistant, the nurse, constituted the health delivery system which was automatically respected. The doctor was in control of the hospital, the practice of medicine and all public health measures.

As the community unit grew larger, cemented together by ever easier and more efficient travel and communications, not only the relative importance of local home rule and the town meeting decreased proportionately, but the ability of any one doctor or group of doctors to act as a unifying and correlative force became strained to the point of breakdown. Along with the technical advances in travel and communications, the technicologic explosion occurred also in all phases of the field of Health thus preoccupying the doctor at the very time that he "should have been" concerned with the methodology of expanding the health care system in terms of increasing specialization, needs to correlate the various specialties and filling various areas of vacuum resulting from expansion of the health needs. At this point one could take the fault-finding approach in a poor attempt to describe what has transpired, or one could more logically try to understand the role of Health in the larger context of the overall change in our society.

The fault-finding approach takes an apparently different form varying with "where it's coming from." The doctor fault-finder will bemoan the loss of control of hospitals by claiming the successive abrogation of responsibilities on the part of doctors by giving birth to hospital administrators, who in their natural growth rebelled against the doctor until maturity dictated that the delivery system depends upon joint action. Rather, the technologic aspects of the practice of medicine have become so involved that the doctor is in imminent danger of becoming a mere technologist. The rapidly increasing costs of technology in terms of both materiel and labor have driven the non-doctor health planner fault-finder to claim that the doctor has accomplished all these increases as a self-serving endeavor. However, the health planner, with the point of view of arbitrarily cutting costs in response to an arbitrary political dictum on the excuse of fault-finding the doctor, is certainly no less susceptible to the accusation of political self-aggrandizement by making cost-cutting Brownie points. The facts of the matter are that Doctors are certainly no more self-seeking than many and probably less so than most. Doctors are certainly not in the forefront of free-riders, free-loaders or political payoffs.

However, in the context of the overall changes in our Society, it must be understood that the vast and sudden expansion of our technology, where 80% of the total historical world production of scientists are alive today and more than 50% of mankind's total technicologic advance has occurred during the present century, has also involved Medicine, the Medical Profession and Health Planners. What has occurred is a big picture of ever increasing size with the creation of new requirements for new types of jobs, vocations and dedications in increasing variety. Who in 1900 would have dreamt of the desirability of a physicist in the Department of Radiology? Or an HSA?

In an attempt to improve the health delivery system a few things are beginning to become increasingly clear. Small minds obsessed with fault-finding will not see the "big picture," much less identify the various components which will have to be modified or created to develop a more efficient health delivery machine. Likewise, as the knowledge of, and cost of therapeutic medicine sky-rockets, there will be a cost need either to change our entire system of free enterprise or decrease the need for therapeutics by developing prevention. Our New England heritage teaches that "an ounce of prevention is worth a pound of cure," is jarred by the aphorism "who controls the Health controls the people," and opts for big minds planning for increased efficiency in a competitive delivery system as well as striving for wider prevention of disease.

Adam Wesolow, M.D.

*Chairman, Dept. of Surgery*
*The Hospital of St. Raphael*

## Two-Dimensional Scanning of the Heart

Echocardiography, a well-established, safe procedure for examining the heart, has become ensconced in the everyday practice of cardiology. It has been proven to be reliable in the diagnosis of mitral stenosis, atrial myxomas, pericardial effusions, the ubiquitous syndrome of prolapse of the mitral valve, idiopathic hypertrophic aortic stenosis, rupture chordae tendineae, and numerous other cardiac lesions which have been reviewed elsewhere in this journal.

The once "innocent murmur" may not be so innocuous. Likewise the guessing game of what the origin of some murmurs is is now more precisely determined with the sound wave technique.

A cardiac examination is incomplete unless an echocardiographic study is included. It is a necessity for the confirmation of suspected cardiac lesions and the discovery of unsuspected abnormalities.

During the past eight years our enthusiasm has been somewhat tampered by some of the limitations of this study. For example: the diagnosis of left ventricular aneurysms, abnormal motion of the left ventricular wall, estimation of orifice size of a valve, and estimating the severity of mitral stenosis, have been all flawed with difficulties with the standard M-mode technique. Currently an extension of the echocardiographic devices has come on the scene: Two Dimensional Echocardiography or Cross Sectional Echocardiography. By employing the same sound waves as used with our traditional M-mode echocardiographic studies, and by the modification of the instrumentation, a true picture of the heart can be obtained. The current M-mode tracings are difficult to visualize and confusing to the physician as they do not look like the heart. Cross sectional echocardiography resembles a cross section of the heart which the physician can clearly identify.

This new technique is more true in representing the cardiac structure, rather than "shadows," of an angiogram or a nuclear scan.

Dr. Roberts describes cross sectional echocardiography as, "Echocardiography is a walking autopsy of the heart."

With the technique of cross sectional echocardiography, various axes of the heart can be visualized. For example: in an apical view the four chambers of the heart are seen with their valves and septum. Measurements of these chambers and valve orifices compare favorably with the "gold standard" of the angiogram.

Ventricular aneurysm, wall motion, (left ventricular function), intraventricular clots and tumors, orifice size, as in mitral stenosis, can be accurately assessed. Visualization of the left main coronary artery has been reported. The earliest diagnosis of acute myocardial infarction can, in many cases, be achieved before enzyme or ECG changes. The diagnosis of endocardial vegetation by the M-mode technique is estimated to be 40% as compared to 70% by the two dimensional technique.

Cross sectional echocardiography is still in its infancy and its enormous potential as a diagnostic tool will be soon forthcoming. Presently most major medical centers in the United States and many hospitals in Connecticut, are actually using this new method. It will not replace the M-mode, but will be used in conjunction with it. Nor will it replace cardiac catheterization, but make the indications more selective.

Siegfried J. Kra, M.D., F.A.C.P.

### "FOLLOW-UP OF CANCER" Booklet Still Available

"Follow-up of Cancer: A Handbook for Physicians" is still available from the CSMS office, 160 St. Ronan Street, New Haven, CT 06511, or from the American Cancer Society, Connecticut Division, Inc., 14 Village Lane, P.O. Box 410, Wallingford, CT 06492. The handbook consists of protocols for the follow-up of cancer in its major sites. The booklet will be sent without charge to physicians or students upon request.

## SUMMARY OF PROCEEDINGS HOUSE OF DELEGATES—SEMI-ANNUAL MEETING

### North Haven - November 16, 1978

### In Memoriam

Immediately prior to the consideration of business, a moment of silence was observed in memory of Dr. David A. Grendon, Sharon, the former Speaker of the House and Chairman of the Council, who had died in July, 1978.

### Reports and Resolutions

The House of Delegates received reports from the President, the Council, the AMA Delegates, and the Executive Director. Also received were a number of resolutions submitted by the Connecticut AMA Delegation and individuals.

### Principal Actions Taken

(a) **Report of the President, Jerome K. Freedman, New Haven:** The House VOTED to accept the report of the President which reviewed Society activities over the past six months, highlighting the following items: the naming of the financial aid fund to medical students to the "David A. Grendon-CSMS Financial Aid Fund to Medical Students"; commended the CME activities in Connecticut, explained the Second Opinion Program as it will operate in New England, reported on the experience of the Professional Liability program during the past year; reported a slight increase in AMA membership in Connecticut; commended the voluntary effort in Connecticut in the cost of medical care and also the joint seminars being sponsored by the Connecticut Hospital Association and CSMS.

(b) **Budget for 1979:** The House VOTED to approve the budget for fiscal 1979, as prepared and recommended by the Council, and to continue membership dues at $100. in 1979.

(c) **Resolution on HEW Second Opinion Program for Medicare and Medicaid Patients:** Following a hearing on the subject, the House VOTED to adopt the following substitute resolution:

RESOLVED: That the Connecticut State Medical Society reiterate its support of the concept of medical consultation. The HEW Second Opinion Program is superfluous, representing, as it does, a potentially wasteful duplication of what is already current and accepted medical practice.

(d) **Proposed Amendments to the Bylaws:** The Council submitted several Bylaw amendments which relate to simplifying the approval of Life and Student membership; reducing the size of the quorum for Council meetings; and expediting the acceptance of resignations and appointments to CSMS committees. These amendments were placed on the table for action at the next meeting of the House of Delegates and will be published in the Journal at least once prior to that meeting.

(e) **Connecticut Medical Political Action Committee (COMPAC):** The House VOTED to approve the Council recommendation that $1,000. be contributed to COMPAC through the appropriate channel permitted by state law to be used for administrative purposes and is in lieu of any "in kind" or other assistance.

(f) **Administrative Organization and Planning:** At the meeting of the House of Delegates on May 3, 1978, the House adopted a resolution recommending that the Council continue and intensify committee review procedures and make recommendations, where needed. The Council's Subcommittee on Administrative Organization and Planning has been studying committee procedures and submitted a report which was approved by the Council and transmitted to the House with the recommendation that it be approved. The House VOTED to approve the recommendation of the Council and approved the report with a minor amendment. The report follows:

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1) It is essential that each County send a representative to the Meeting of the Subcommittee on Preliminary Studies of Nominations. Prior to the meeting the County representatives are urged to identify potential candidates from their counties and determine their committee interests, willingness to serve, and eligibility for membership on the State Committees.
2) The President of the Society, together with his appointed Delegates, shall monitor committee activities during the year.
3) Acting as Chairman of the Subcommittee Meeting, he will inform the members of the Subcommittee of his evaluation of the status, the interim activities, and the needs for the forthcoming year of each CSMS committee. The Subcommittee shall give serious consideration to CSMS members who are not members of the Council when filling vacancies on the State Committees.
4) Members of the Council shall not serve on more than two standing State Medical Society committees as a voting member.
5) The following additions to our General orders are recommended:
   a) Committee Chairman:
      1) No Committee Chairman shall serve more than 3 consecutive years as Chairman.
      2) Any committee reports to the Council which recommend action shall be presented in person by the Chairman of the Committee or his Delegate.
      3) The chairman or his designate shall be prepared to testify as necessary regarding State legislation which interacts with his Committee activities.
      4) He shall be prepared to amplify, if necessary, his Annual Report to the House of Delegates.
      5) He shall insure that a Vice-Chairman and Secretary are chosen by the Committee at its first meeting.
   b) Committee Members:
      1) All Members are expected to attend all meetings. Failure to attend at least 50% of the meetings, or three consecutive meetings without a valid excuse, will constitute resignation from the Committee.
      2) Initial appointment to the Committee is made by the House of Delegates. Subsequent re-appointment is made by the House of Delegates in consultation with the Chairman of the Committee.
      3) Committee Members shall be prepared, if practical, to testify as necessary as regarding state legislation which interacts with their committee activities.

(g) **Interim Change in CSMS Officers:** It was VOTED to confirm the interim appointment of Charles M. Krinsky, New London, as Vice-Speaker of the House of Delegates until the next meeting of the House of Delegates.

(h) **Voluntary Fee Restraints:** The House VOTED to approve a resolution with minor amendment by the President which reads as follows:

RESOLVED: That the House of Delegates of the Connecticut State Medical Society (in the spirit of cooperation with the recent request of President Carter) supports the concept of voluntary fee restraints and urges that the members of this Society exert their best efforts in such restraint.

(i) **Questionnaire of CSMS and AMA Policies:** The House VOTED to refer to the Council for consideration a resolution which urged that a questionnaire be drawn up and disseminated to all CSMS members eliciting their opinions about activities and policies of CSMS and of the AMA.

### Recognition of Service to the Society

#### OFFICERS

Carl W. Johnson, Thompsonville—Treasurer, 1974-1978

Hilliard Spitz, New London—Councilor-at-Large, 1977-1978

#### COUNTY COUNCILORS

HARTFORD: Roger S. Beck, Hartford—Associate Councilor, 1977-1978

MIDDLESEX: W. Raymond James, Essex—Councilor, 1973-1978

NEW HAVEN: John J. Mendillo, New Haven—Associate Councilor, 1974-1976; Councilor, 1976-1978

WINDHAM: Charles J. Middleton, Danielson—Associate Councilor, 1976-1978

### Special Awards

(a) M. David Deren, Bridgeport: Presented with a framed resolution outlining his dedicated and valuable efforts on behalf of the Society in developing the successful professional liability program for members of the Society.

(b) William R. Richards, Hamden: Presented with a framed resolution granting him lifetime membership in the House of Delegates for his dedication, service and assiduous efforts on behalf of the Connecticut State Medical Society.

# PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

## OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

### ALLERGY

Allergist, to take over well-established practice. Retiring MD will stay on and introduce to his patients. Locum Tenens also available for the Feb.-March 1979 period. Send CV to CSMS/NB to be forwarded.

### EMERGENCY ROOM

Full service community hospital in suburban setting, with university medical and research centers nearby. Staff of 6 full-time physicians: 34,000 annual visits. Competitive salary for career oriented individual. Please send resume to: Chief, Emergency Services, Meriden-Wallingford Hospital, 181 Cook Ave., Meriden, CT 06450

Small community hospital in Northwest CT seeks full-time ER physician. Hours flexible, full fringe benefit program competitive salary, paid malpractice, meeting and vacation time. An opportunity to develop Emergency Medicine into a full hospital service. Attractive rural community in superb recreation area within easy reach of major cities. Send CV to Richard S. Dutton, M.D., Winsted Memorial Hospital, Winsted, CT 06098

### FAMILY PRACTICE

Family Practice on Country Estate. Well-established home/office practice in Northeastern CT. Elegant circa 1820 home with modern office ell. 108 rolling acres. Modern community hospital nearby. Retiring physician will assist with patient introductions. Send CV to CSMS/PREC to be forwarded.

3-man Family Practice group on eastern CT shoreline looking for fourth man. Family Practice and industrial. Salary first year, partnership thereafter. Mostly office practice. Send CV to CSMS/NN to be forwarded.

Family Physician to associate with one other, age 36, in South Central CT town. Financial and office arrangements as mutually agreeable. Congenial atmosphere in town and hospital. Forward CV to CSMS to be forwarded. Opp. FP/LL.

### INTERNAL MEDICINE

A two-man partnership is looking for a third to fill void left by recently deceased partner. Excellent diagnostic setup. General adult medicine. Cultural advantages of New Haven, relationship with Yale-New Haven Hospital. Contact Marvin Cousins, M.D., days (203) 865-5111; evenings (203) 393-1324.

**Primary Care Physician:** General Internist or Board qualified Family Physician for expanding Group Practice in Eastern CT. Willingness to practice good medicine in rural environment essential. Close to University campus at Storrs. Privileges in Medicine and Coronary Care at Windham Hospital. No OB or Ped. Salary with house provided first year, partnership thereafter. Contact John Hayes, M.D., Windham Medical Group, (203) 423-9764.

### INTERNAL MEDICINE

St. Francis Hospital seeks a general internist to direct its ambulatory patient care and teaching program. 650-bed teaching hospital affiliated with the Univ. of Conn. Newly acquired modernized facility connected to the hospital. Dept. of Medicine has active teaching programs at all levels, student, housestaff, and fellowship. Strong focus on general internal medicine and medical subspecialties, staffed by full-time and practicing physicians. Applicants should be bd. cert. in medicine or recent trainees intending to be cert. Contact J. David Schnatz, M.D., Dir., Dept. of Medicine, 114 Woodland St., Hartford, CT 06105.

### PEDIATRICS

Rapidly growing two-man pediatric practice in Central CT seeking third man for July 1979. Send CV to CSMS/KMR to be forwarded.

Established three-man pediatric group seeks a replacement for associate leaving for fellowship in July 1979. Good salary, early partnership offered. Opportunity includes full teaching hospital affiliation. Contact Peter J. McLoughlin, M.D., 1984 Park Ave., Bridgeport, CT 06604.

Two Pediatricians aged 33 with rapidly expanding practice in Southeastern CT seek young, Bd. elig. and/or cert. third associate. Contact: David M. Rinzler, M.D., or Dennis S. Long, M.D., Rt. 12, Torrey Park, Gales Ferry, CT 06335.

## PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

### ANESTHESIA

Available now. Age 38. Conn. license. AB-elig. MD from Iran. Int. at Bridgeport Hosp. Res. at NY Hosp.-Cornell. Fellowship at Flower & Fifth Ave. Hosp., NY, also VA Hosp., Manhattan. Wishes solo or grp. practice in large community. Parvin Javadi, M.D., 57 Montague St., Apt. 9G, Brooklyn, NY 11201.

Available anytime. Age 34. AB-elig. Presently in practice. MD from India. Int. at St. Joseph's, RI. Res. at Cambridge Hosp., Mass. Fellowship at Boston City Hosp. Special interest in teaching, research and clinical practice. Geeta R. Trivedi, M.D., P.O. Box 508, Norwich, CT 06360

July '79. Age 29. Nat'l. bds., elig. MD from Hahnemann Med. Coll. Int. at Harrisburg Hos. Res. and fellowship (ped., cardio-thoracic anesthesia) at M.S. Hershey Med. Ctr. Wishes grp. practice in med. community. Daniel L. Derewitz, M.D., University Manor Apts., #100, Hershey, PA 17033.

Dec. '78. Age 41. Conn. license. Nat'l. bds., cert. Presently in practice. MD from Taiwan. Int. at Northeastern, PA. Res. at Dalhousie. Wishes grp. practice in med. community in Ct. Contact CSMS/Anes.-SWW.

### INDUSTRIAL MEDICINE

Available immediately. Private practice in Conn. since 1943. MD from Toronto. Int. at St. Raphael's. Has had many papers published. Had a Medical Column in three local newspapers. At present book in publication. Affiliated with the Conn. Occupational Medical Association. Contact CSMS/IND-RIS.

### INTERNAL MEDICINE

Oncology: July '79. Age 31. Nat'l. bds., cert. Presently in practice. MD from Northwestern. Int. at Passavant Med., IL. Res. at Cornell Cooperation Hosp's. Fellowship at Mt. Sinai Hosp., NY-SUNY. Wife is Surgeon. Wishes grp., assoc. or institutional practice in CT. Daniel J. Arnold, M.D., 445 E. 68th St., #12M, NY 10021.

# Irradiation Related Thyroid Cancer

## History and Current Recommendations

RICHARD M. STOCKWELL, M.D.

**ABSTRACT—Seventy-one years ago irradiation was first reported in the treatment of thymic enlargement. Twenty-eight years ago Duffy and Fitzgerald alerted the medical world to the possibility that this practice might result in thyroid cancer. Subsequent studies have confirmed beyond doubt the cause and effect relationship between irradiation of the upper body in early life with the development of malignancy following a latent period at times of more than 30 years. This review traces the origin, historical development, and major complication of an abandoned therapeutic modality administered to a group which probably numbered one million nationwide. It discusses the currently recommended procedures for management of exposed patients.**

### History of Irradiation for Benign Disease of the Thymus, Head and Neck

In 1907, Friedlander presented a paper entitled "Status Lymphaticus and Enlargement of the Thymus, with Report of a Case Successfully Treated by the X-ray," before the Academy of Medicine of Cincinnati, Ohio.[1] This author reported on a male child about five weeks old. Several quotes follow:

"Based on the finding of the greatly enlarged thymus, with the cough, the inspiratory stridor, the asthmatic attacks, the pressure cyanosis, the enlarged spleen and lymphatic glands, with absence of cardiac or pulmonary lesion, the diagnosis of status lymphaticus and enlarged thymus was made. The only medication ordered at this time was sodium bromide in one grain doses.

"During the next few days the child's condition grew steadily worse. The cough increased in frequency, and the asthmatic paroxysms became worse. At times these paroxysms lasted over an hour, being accompanied by marked cyanosis and leaving the child completely exhausted. Indeed, on several occasions after these paroxysms it seemed that respirations would cease. . . . "

Subsequently x-ray therapy was given. This was followed by marked improvement in the clinical condition of the child which rather quickly returned to normal. When older, the patient required the removal of tonsils and adenoids: "Again, the fact that the child could successfully withstand such a trauma as the removal of tonsils and adenoids without shock would speak for the resistance fully up to normal. Under all circumstances, therefore, the results of x-ray therapy with reference to the enlarged thymus are most gratifying and encouraging. The procedure is of course infinitely simpler than the removal of the thymus by surgical means, and it would seem justifiable to hope that in x-ray we have a valuable therapeutic resource for the treatment of what has hitherto been considered an almost desperate condition."

As years passed, x-ray treatment gained popularity. By 1924, indications for its use in certain benign conditions were well worked out and were published by Dr. Witherbee of New York City:[2] "1) Where an anesthetic or operation is contraindicated; 2) those cases past middle life where hemorrhage may cause complication due to a mild fever or severe arteriosclerosis; 3) patients whose tonsils are imbedded in infected tissue in which the operation may cause dissemination of septic emboli into the blood and lymph streams, thus producing lung abscess, septicemia, endocarditis, etc.; 4) patients whole adjacent lymphatic structures (not removable by operation) are markedly infected. . . . "

### Irradiation and Thyroid Cancer: Historical Development

Duffy and Fitzgerald[3] were the first to call attention to the problem in 1950 when they reported 28 cases of cancer of the thyroid in children seen at the Sloan-Kettering Institute between 1932 and 1948. Nine of these children underwent thymic irradiation between the fourth and eighteenth month of life. Only one of the 28 came from a goiter endemic area and only two had a family history of thyroid disease. Thus, prior x-ray exposure was by far the most important risk factor. By the time Duffy and Fitzgerald pointed out this association, 43 years had elapsed since Friedlander had published his report in 1907. During the 1950's other important papers were written implicating x-ray treatment of the young with thyroid carcinoma.[4] [5] [6]

Hempelmann *et al.*[7] at Rochester studied nearly 2900 young adults who had received irradiation treatment in Upstate New York. Questionnaires mailed to subjects, supplemented when necessary by examination of patients and tissue, formed a core of information collected between 1954 and 1974. By

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RICHARD M. STOCKWELL, M.D., Assistant Professor of Medicine, University of Connecticut School of Medicine, Farmington, CT.

comparing the 2872 patients with their 5005 non-irradiated siblings a clear association between irradiation and thyroid neoplasia was documented. Twenty-four of 76 lesions were found malignant at operation in the study group. More than half of these occurred among the 10% treated with much larger-than-average x-ray levels by a single radiologist. None was observed in sibling controls. Benign adenomas were clearly more frequent in the radiated group. Thyroiditis was found in two patients.

Later authors include DeGroot and Paloyan[8] in 1973 who found 20 of 50 patients with carcinoma of the thyroid in their Chicago practice had known previous x-ray therapy an average of 20 years before. Nearly all those patients were less than 35 years old. Nowhere has the problem been more widely recognized than in Chicago where at one major institution the practice of irradiation for benign head and neck problems continued until 1962.[9] In Figure 1 the developments since Friedlander's first publication are displayed graphically as a time-line.

In 1976, Favus *et al.*[9] reported from Chicago on experience gained by evaluation of 1056 younger adults who had received irradiation usually for enlargement of tonsils and adenoids. The population at risk was irradiated between 1939 and 1962 usually with 200-KV radiotherapy. Clinical evaluation of the irradiated gland included pertinent history, thyroid imaging ($^{99m}$Tc pertechnetate) and physical examination by one or more physicians unaware of scan results. If an abnormality was found by thyroid scan that was not apparent on initial examination, the patient's thyroid was examined again by one or more physicians. Evaluation of these 1056 subjects revealed thyroid abnormalities in 278 or 26.3% of which 145 were single and 133 were multiple. Of the single nodules, only half were detected by physical examination. The scintigram detected abnormalities in 99 who were thought normal on palpation and an additional 15 whose abnormalities on palpation were not thought nodular. The examiner's ability to find nodules was clearly enhanced by the scintigram.

Surgery was recommended for nearly all patients with abnormalities by scan/or physical examination. One-hundred-eighty-two operations were reported. Well-differentiated carcinoma was found in 60, or one-third, 28 of which were multicentric within the thyroid gland. There were 23 papillary, three follicular and 34 papillary-follicular tumors. Anaplastic carcinoma was not identified. Even though no distant metastases were found, lymph node involvement was demonstrated in 17 patients. The concept

Figure 1
Historical Relationships Timeline
(Comparing dates of publications)

| *Years from publication of first reported x-ray treatment of thymus* | *Year* | *Author* | *Event* |
|---|---|---|---|
| 0 | 1907 | Friedlander | Irradiation therapy first used for thymic enlargement |
| 17 | 1924 | Witherbee | Indications for Roentgen therapy in chronic tonsillitis and pharyngitis published |
| 43 | 1950 | Duffy,<br>Fitzgerald | In 28 cases of thyroid cancer in children, previous x-ray therapy is the most prominent identified risk factor |
|  | 1952 | Winship | Further important publications relating irradiation to thyroid malignancy |
|  | 1955 | Clark<br>Simpson |  |
|  | 1963 | Hempelmann et al. (1954-1975) |  |
|  | 1973 | DeGroot, Paloyan |  |
|  | 1976 | Favus et al. | Evaluation of 1056 irradiated patients including 182 operations |
| 70 | 1977 |  | Department of Health, Education and Welfare distributes information for physicians regarding evaluation and management. Publicity programs are recommended. |

that thyroid neoplasia is less common in multinodular glands proved invalid in this study. Seventy-two percent of carcinomas were associated with benign adenomas. In fact, when carcinoma was found, 47% of the time it was not within the lesion detected clinically. The overall frequency of carcinoma in the 1056 patients was about 9%.

### Histologically Malignant Thyroid Nodules versus Clinical Cancer

Autopsy series of unselected patients in at least eight different U.S. cities and counties[10] have shown a significant incidence of occult thyroid nodules with malignant histology. These studies report incidence ranging from 0.9% in Cleveland to 5.7% in Olmstead County, Minnesota. The variation reported is more than six fold, probably in part due to differences in the study methods. However, the frequency of such malignant histology appears to be significantly higher in selected population groups. Sampson *et al.*[11] studied 3067 thyroid glands at autopsy from Japanese irradiated and not irradiated at Hiroshima and Nagasaki. The prevalence rate in 1096 *not* irradiated was 17.9%. Hempelmann *et al.*[7] (whose studies were based on operative rather than autopsy material) found the prevalence of thyroid carcinoma in females 2.3 times that of males which approximates the sex ratio recorded by many others. Their finding that Jews had a 3.4 fold greater risk than non-Jews was a statistic not corroborated by most authors. Factors other than irradiation play a role in determining the incidence of malignant histology within thyroid nodules of varied population groups. Despite the common autopsy finding of malignant histology, most populations, including the Japanese, have a low incidence of clinical thyroid cancer. In the United States one might expect to encounter one case in 27,000 individuals in the general population.[12] Sampson *et al.* conclude: "The factors that cause a small tumor to form may be dissociable from those that make it grow to be a clinically evident tumor or to be aggressive enough to cause death."

### Current Status and Recommendations

The Department of Health, Education and Welfare has recently published recommendations for physicians concerning this important problem.[12] The result of a workshop held in 1975 which included experts on various aspects of thyroid disease, this monograph provides an official guide which should be obtained by every physician who anticipates caring for patients with the problem.*

Selected data is summarized from this report: Although it is clearly desirable to recall for examination all patients who had received irradiation, and all hospitals, departments of radiology or physicians who still have appropriate records should institute a recall program, in general a public education approach is considered more appropriate because of the great practical difficulties in such recall programs. Practicing physicians "should be informed and provided with expert advice . . . this educational effort should be carried out by state and national medical organizations, state and local health departments, the American Cancer Society, and the National Cancer Institute . . . . After the practicing physicians have been appropriately informed, a well-planned, low-keyed program should be launched to educate the public about the problem stressing the need for medical examination, the low incidence of malignancy and the high probability of cure."[12] Thus, a major responsibility for care of this problem falls on the individual practitioner.

The report stresses the need for including a question about prior irradiation as a part of any patient's routine history. In addition, questioning the patient's parents, if available, is of great value since many patients are unaware of irradiation procedures carried out in their own infancy. When positive, further investigation should be made with the patient's former physicians, when practical. The physical examination and laboratory studies are both important in the workup. The degree to which thyroid scans are utilized varies as "some physicians believe that radioisotope scans contribute little useful information regarding possible thyroid malignancy and that most discrete nodules should be removed without consideration of a scan. Others prefer to obtain a scan on all patients with a history of irradiation or suspected thyroid disease whether or not palpable nodules are present . . . . *If a scan is to be performed the preferred scanning agents are either technetium-99m pertechnetate or iodine-123* since both deliver much lower radiation than does iodine-131 . . . .

"All individuals with a history of head or neck irradiation should be considered an increased risk of developing thyroid cancer and should be examined periodically (at least every two years) indefinitely . . . .

"On the basis of physical examination, patients may be divided into three categories:

1) Those with no visible or palpable abnormalities;
2) Those with discrete nodules or nodules on palpation; and
3) Those with diffuse enlargement of the gland without palpable nodule."

For patients in category 1), the majority of consultants felt thyroid scan was not mandatory "if palpation of the gland by an experienced examiner reveals no abnormalities. Careful reexamination is recommended at least every two years." If a scan is performed and is considered normal, the patient should have his thyroid examined every two years. If it is equivocal or shows a hot area, again most consultants felt the patient should be reexamined only, but, with such findings, after one year. If a scan shows a cold or nonfunctional area in a gland which has no palpable abnormality, the patient should be examined again very carefully "preferably by more than one examiner experienced in examination of the thyroid." Usually such reexamination has revealed a small nodule which was missed on first palpation. "These patients should be considered for surgical exploration." If no nodule is felt, the three options of followup with palpation yearly, suppressive doses of thyroid hormone, and surgical exploration are discussed.

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*Available from National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20014—Information for Physicians, Irradiated-Related Thyroid Cancer, DHEW Publication No. (NIH)77-1120; also available is a pamphlet which has been written for distribution to patients entitled: Did You as a Child or Young Adult have X-ray Treatments Involving Your Head or Neck? DHEW Publication No. (NIH)77-1206.

For category 2), patients (palpation of whose thyroid glands reveals one or more firm, discrete nodules) most consultants recommended removal regardless of findings on the scan.

Assessment of patients in category 3) is also considered in detail.

## Discussion

Management of the thyroid nodule in a nonirradiated subject has been controversial for many years. Disagreement is found when considering irradiated subjects as well. Underlying the controversy is a discrepancy between the high incidence of malignant histology associated with an exceedingly low rate of morbidity and mortality from thyroid carcinoma. Studies involving patients in Chicago[9 13] have clearly shown an increase in the incidence of malignant thyroid histology in patients who had had neck irradiation in childhood. In addition, radiotherapy has been shown by others to be a highly significant risk factor in several groups of patients undergoing surgery for thyroid malignancy. Malignant histology does not equate with clinical cancer at the time of or soon after diagnosis, and radiation is not the only factor which relates to malignant histology. The group operated upon in Chicago had a mean age of 32 years whereas the autopsy series which reported unselected subjects in a given area covered a much older group. However, other authors have shown a very low long term mortality in patients proven to have well-differentiated papillary or mixed thyroid carcinoma below the age of 40.[14 15] There is indeed fear that a large number of patients with irradiation-related malignant thyroid histology may develop symptomatic malignant disease later on.

Irradiated patients have a clearly increased incidence of benign adenomas and carcinomas primarily of the papillary and mixed papillary-follicular types. Though not numerous in most studies of irradiated patients, follicular carcinoma is also more common than in the control population. Thyroiditis has been reported occasionally many years after irradiation as well.[7]

Fortunately, carcinoma of the thyroid has not proven to be a significant complication of radioactive iodine (RAI) therapy for hyperthyroidism. A critical radiation dose appears to be exceeded by RAI therapy beyond which carcinoma ceases to be a problem, probably because of ablation of thyroid tissue.

Although there is controversy, many recommendations, procedures and steps in the decision-making process are reasonably clear. Unnecessary irradiation must be avoided. The public should be and is being alerted to the problem. As a consequence, patients will be seeing their physicians in increasing numbers for evaluation. Primary physicians and many others should search out and pursue a history of irradiation in their patients. Those with a history of x-ray therapy need to be followed with regular examination of the thyroid at intervals described which never exceed two years. Other laboratory parameters are relatively unimportant. At least for the majority of the irradiated patients, those without nodular abnormalities, the primary physician will be providing on-going observation. He or she must remain current and skilled in examination techniques. Superior record keeping including measurement, description and diagramatic representation of any lesion is well worthwhile. In discussing thyroid cancer with this often worried group of patients the physician may wish to emphasize the excellent prognosis in this slow-growing disease compared with malignancy arising from other sites with which people are more familiar.

Since the Department of Health, Education and Welfare published its information for physicians on this subject, reports have appeared in the literature which analyze large groups of patients operated on for thyroid cancer. These show that patients with papillary cancer who were treated with thyroid hormone in addition to surgery fared better than those who were not.[14 15]

Whether or not the cost, morbidity and mortality of surgery in a given patient are justified depends on a number of factors. The biological potential of the tumor to cause disease and death is crucial but not yet well understood in irradiated patients. Clinical investigation leading to a better understanding of this potential should lead to an increasingly rational approach toward the care of these patients. The experience of the surgeon must also be weighed into a decision. Selection of patients for surgery *versus* medical followup requires as much historical data as can be made available, careful examination, judicious use of laboratory parameters, up-to-date information as to the state of the science and careful consideration of all the facts by a seasoned clinician. Only by such an approach can the profession best serve the needs of these people without compounding one therapeutic misadventure with another.

### REFERENCES

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# Cloacogenic Carcinoma of the Vagina

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**ABSTRACT—A case of transitional cloacogenic carcinoma of the vagina is presented, and its presence in this rare site is discussed. Transitional cloacogenic carcinoma must be considered as a rare cause of vaginal bleeding and dyspareunia.**

In recent years, transitional cloacogenic carcinoma originating at the anorectal junction has become recognized as a distinct pathological and clinical entity.[1-6] In 1956 Grinvalsky and Helwig[7] drew attention to the annular zone of transitional epithelium separating the endodermal from the ectodermal portions of the anorectum. They pointed out that this zone is a remnant of the embryonic cloaca which gives rise to neoplasms of varied histology, and they categorized them as "transitional cloacogenic carcinomas." The vast majority of these neoplasms present with anorectal signs and symptoms, and are symptomatically and morphologically indistinguishable from the more common adenocarcinomas and keratinizing squamous carcinomas of the anorectum. A search of the English literature has failed to reveal any previous description of primary cloacogenic carcinoma of the vagina.

It is the purpose of this paper to present a case of cloacogenic carcinoma of the vagina, and to discuss its origin at this rare site.

## Case Report

M.R., a previously healthy 60-year-old white female, was admitted to the hospital on October 4, 1976 with a history of vaginal bleeding for the preceding month, and mild dyspareunia for the preceding year. Generally she felt well. Examination revealed a stony hard 8 x 8 cm ovoid mass involving the posterior vaginal wall which was roughened and puckered over it, with no ulceration. Similar poorly-defined tissue was also palpable in the anterior

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vaginal wall near the urethral orifice. The internal pelvic organs were normal.

The anorectal mucosa was normal in appearance, and free of the mass. Biopsy of the mass via the posterior vaginal wall revealed cloacogenic carcinoma of the basaloid type (Figure 1) (Figure 2). Cystoscopy revealed a firm fixed nodular mass along the anterior vaginal wall, extending beneath the urethra, which, together with the bladder floor, was distorted by the mass. The urethral and bladder mucosa were intact with no evidence of intraurethral or intravesical neoplasm. Chest X-ray showed typical hematogenous metastases throughout both lung fields (Figure 3).

Despite combination treatment with Mitomycin, Thioguanine and Fluorouracil, her condition deteriorated. Her final hospital admission was on January 23, 1977 with pulmonary insufficiency and cachexia. She expired on February 9, 1977.

Autopsy revealed three nodules of cloacogenic carcinoma in the posterior vaginal wall and rectovaginal septum, and metastases to the para-aortic and bilateral inguinal lymph nodes, lungs and liver. The rectum, bladder and urethra were free of tumor.

An incidental observation was a rise in serum carcinoembryonic antigen (CEA) from 7.6ng/ml on the first hospital admission to 16.7ng/ml on the final admission. Normal CEA in our laboratory is 0-2.5ng/ml.

## Discussion

Primary cloacogenic carcinoma of the vagina is rare. Klotz et al[2] report three cases (0.8%) with vaginal bleeding in their series of 373 cases and two cases (0.5%) with a vaginal mass. It is not clear

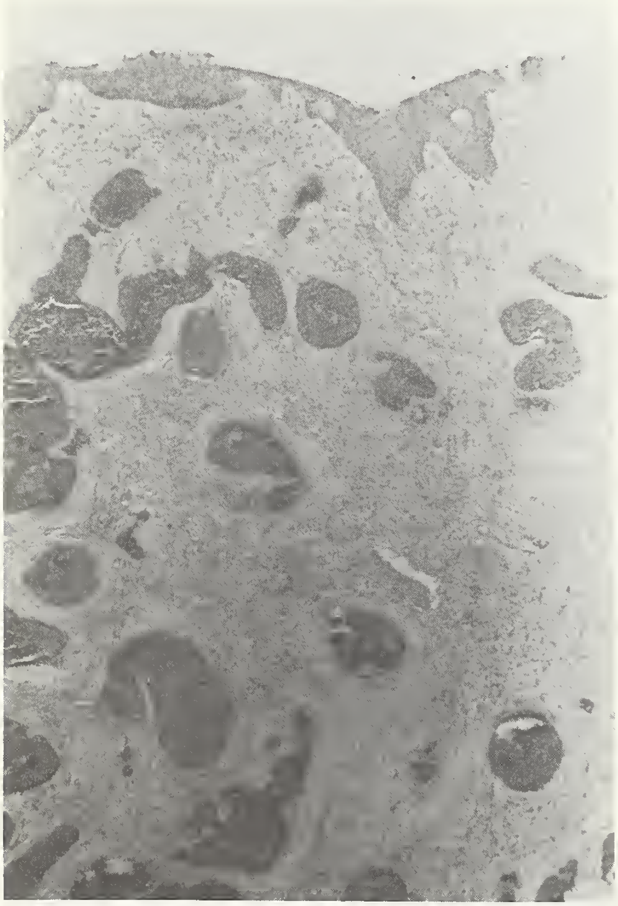

Figure 1
Vaginal wall with numerous masses of small epithelial cells, with peripheral palisading and frequent central necrosis (H + E 100x).

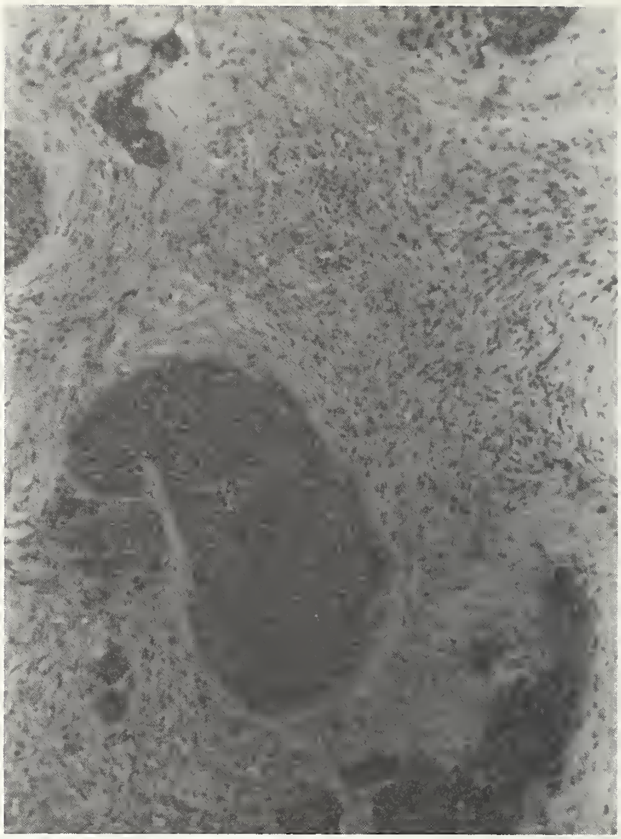

Figure 2
Higher power view of tumerous nest (H + E 100x).

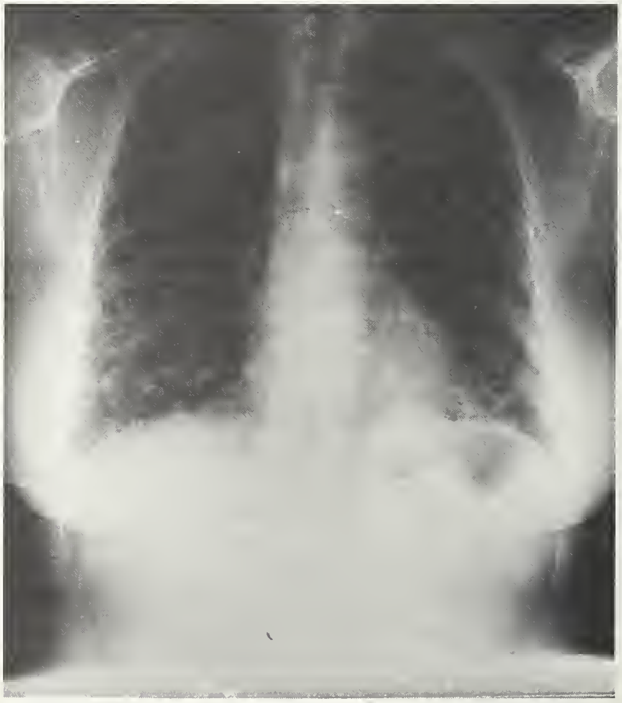

Figure 3
Chest X-ray showing typical hematogenous metastases throughout both lung fields.

whether these lesions were primarily vaginal, or whether they extended to the vagina from a primary anorectal lesion.

Stern and Kaplan[8] investigating concomitant and sequential multicentric carcinomas in the lower genital tract, vulva, perineum and anal canal, studied 6-12 week-old human embryos, and showed that the cervix, vagina, vulva, perineum and anal canal have a common origin from the embryologic cloacogenic membrane. Cloacogenic carcinoma arising in residual cloacal tissue in or adjacent to the vaginal wall would explain the presence of a primary lesion at this site. It should be noted, however, that none of the ten cases reported by these workers had a cloacogenic carcinoma of the vagina; and five cloacogenic carcinomas reported were in the anal canal.

The anatomy of the anal ducts has been studied in detail.[7] They are long tubular structures originating in the transitional cloacogenic zone at the anorectal junction. They follow a tortuous course through the lamina propria, usually caudad, but occasionally cephalad for a short distance, before penetrating the internal anal sphinctor to varying depths; they may, however, extend as far as the adventitial fat.

Cloacogenic carcinoma arising in an anteriorly-situated anal duct in the perirectal fat would provide a second explanation for the lesion involving the posterior vaginal wall without involvement of the anorectum. Carcinoma of varying histology arising from the anal ducts has been well described.[9] [12] In cases of anorectal cloacogenic carcinoma the adjacent structure most commonly involved by direct extension is the vagina, especially if the primary lesion is in the anterior rectal wall or in an anal duct anterior to the rectum. In the latter case the lesion could extend anteriorly into the vagina without involvement of the rectal mucosa.

The clinical significance of this case presentation is that transitional cloacogenic carcinoma may rarely present as a primary vaginal lesion. Its diagnosis should be considered in women 50-70 years of age when other more common lesions of the vagina have been excluded.

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*(I would like to thank Dr. Thomas H. Connell, Jr., for his permission to present this case.)*

# Diabetic Neurosteoarthropathy of the Tarsus

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**ABSTRACT—The incidence of neurosteoarthropathy in diabetes is 0.16% to 2.5%. Three cases are presented here and the pathogenesis of this process is investigated. There is a Mononeuropathy Multiplex of diabetes which affects the peripheral nerves around the tarsus causing a process of continual destruction and repair of these bones leading to a "rocker bottom" type of foot deformity. The two factors which most frequently influence this process are infection and altered perception of weight bearing stresses on the foot. Their exact significance, however, remains speculative. The importance of good diabetic foot care is emphasized. The treatment is preventative. A shoe with SACH Foot and a central rocker is recommended. Occasionally amputation is necessary for the most intractable cases. If feasible, a Symes amputation should be done.**

## Introduction

Diabetic neurosteoarthropathy is also known as the neuropathic foot, diabetic neuroarthropathy and diabetic osteopathy. The basic pathologic process is a disorder of peripheral nerves which produces destructive changes first in the bones of the tarsus and secondarily in the tarsal joints.

Fortunately the incidence of such a deformity was only 2.5% in a series of 500 diabetics[6] and 0.16% in a larger series from the Deaconess Hospital in Boston.[9]

The purpose of these case presentations is to illustrate different points in the pathogenesis, histopathology, and radiology of this condition, to review the literature, and to outline a plan of treatment.

## Case I

M.Z., a 45-year-old white female weighing 250 pounds with adult onset diabetes mellitus for 15 years, was admitted to the Hospital of St. Raphael's on 5/21/76 with the chief complaint of increasingly severe pain in the left foot during the past 30 days. Her left foot had a "rocker bottom" appearance with a totally collapsed medial longitudinal arch, valgus deviation of the forefoot, large calluses under the head of the talus and a two-centimeter ulcer on the medial aspect of the sole of the foot. The ulcer edges were painless but she complained of much pain in the area of the sinus tarsi. Attempted passive motion of the mid-tarsal joints produced severe foot pain. Her dorsalis pedis and posterior tibial pulses were both present and of good quality. Cultures of the foot ulcer showed moderate colonies of pseudomonas aeruginosa and scant colonies of staphylococcus aureus. She was treated with bed rest, elevation, daily warm soaks, and debridement of the hyperkeratotic wound edges. After all cultures became negative, on 11/26/75 an attempt was made to surgically excise the bony prominences that were causing abnormal skin pressure. A triple arthrodesis was performed. She was placed in a cast for 3 months. The ulcer healed without any complications. Five months after the procedure, the pain in the foot recurred. A painful pseudarthrosis was thought to be present in the subtalar joint. She was readmitted on 5/26/77 with her blood sugar ranging between 250 and 275 milligrams per milliliter. The original "rocker bottom" deformity had recurred. She complained of severe pain and tenderness in the mid-tarsal region of her left foot. At this time her right foot was also painful but no trophic ulcers had developed. A BK amputation was performed on the left side. Ten weeks post-operatively, a patellar tendon bearing prosthesis was provided. Her right foot remains free of ulcers but is markedly painful to the point where the patient desires an amputation. A Symes amputation has been considered if the problem worsens.

## Case II

H.M. is a 37-year-old married pregnant black female weighing 250 pounds admitted to Yale-New Haven Hospital on 10/24/77 for control of her diabetes mellitus and for treatment of multiple abdominal skin abscesses. On 9/21/77 she had been admitted to Yale-New Haven Hospital complaining of pain in her right axilla and in her left lower quadrant. She had had 16 previous admissions to other hospitals for uneventful pregnancies, spontaneous abortion, diabetes mellitus, urinary tract infection, carbuncles, amputation of the right fourth toe, and cellulitis of the left foot. During her September 1977 admission, a pelvic ultrasound study revealed the presence of an intra-uterine pregnancy. Her WBC count on admission was 20,500, her fasting blood sugar 273 Mg/ml, her alkaline phosphatase was 102 Bodansky units. Culture

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and sensitivity of the abdominal wall abscesses yielded staphylococcus aureus coagulase positive. The abscesses were drained locally and she was placed on Ampicillin 500 mgm. p.o., q. 6 hours. She was readmitted in October of 1977 for similar abdominal wall abscesses and for similar treatment. An orthopaedic consult was obtained at that time because of the possibility of osteomyelitis of her left foot and because of a slowly growing painless mass on the lateral plantar surface of the left foot measuring 7 x 7 x 2 centimeters (Figure 1). The mass was nontender, it showed no increase in temperature, no redness or fluctuance. It did not transilluminate. Sensation in both feet was grossly present although vibratory sense was not tested. X-rays showed bony abnormalities of the mid-foot with a large adventitious bursa along the weight-bearing plantar aspect of the foot (Figures 1a, 1b).

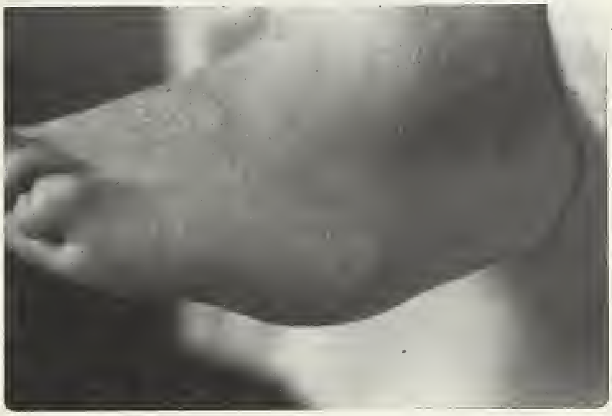

Figure 1
Lateral photograph of the left foot showing a "rocker bottom foot" caused by plantar displacement of the calcaneus and cuneiforms.

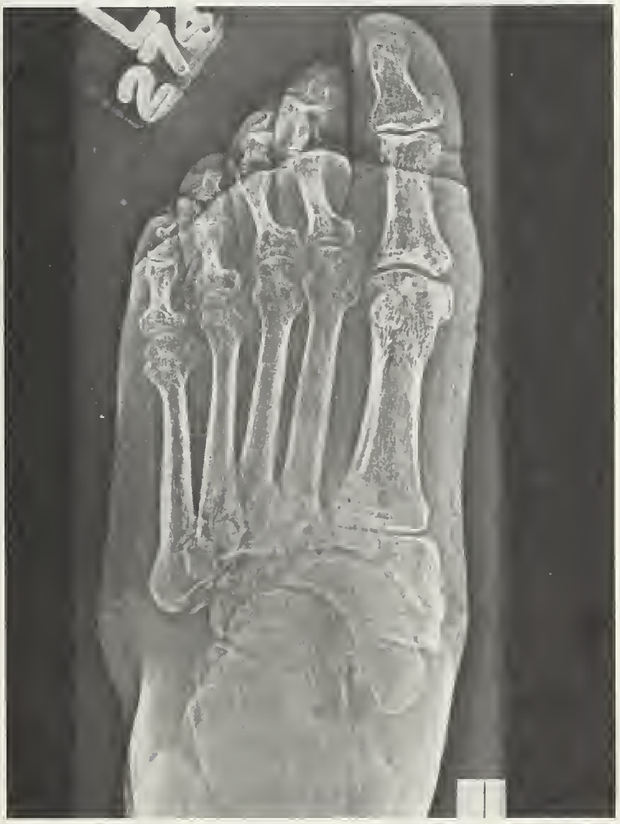

Figure 1a
Anterio-posterior Xeroradiograph showing destruction and displacement of mid-tarsal joints.

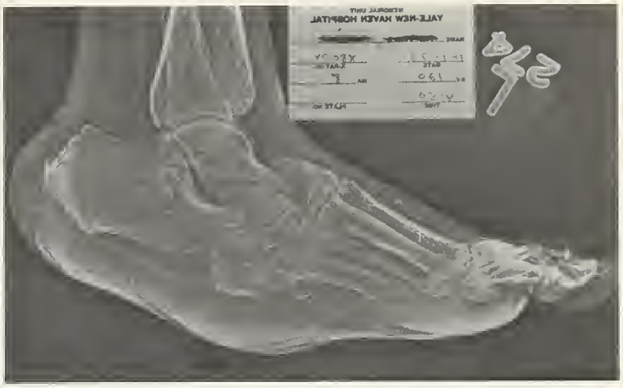

Figure 1b
Lateral Xeroradiograph of the same foot. Notice plantar subluxation of cuneiforms and retrograde displacement of metatarsals.

## Case III

E.K. is a 55-year-old white female with adult onset diabetes mellitus for 7 years admitted to Yale-New Haven Hospital on 11/28/77 for open biopsy of the tarsal bones. In December of 1976 the patient picked a callus from the tip of her 2nd toe causing a paronychia. She was treated as an out-patient with soaks and with Penicillin VK for 4 weeks. Two weeks after the antibiotics were stopped she noted the onset of swelling, redness, and tenderness in her right foot. She was admitted to the General Surgical Service on 2/8/77 with the diagnosis of cellulitis. Blood cultures grew out Group B—beta hemolytic streptococcus. The patient was started on intravenous Penicillin G 8 million units per day for 4 weeks. A bone scan revealed markedly increased uptake in the 2nd and 3rd metatarsals and in the tarsus (Figure 2). The initial x-rays showed some blurring of the cortical margins of the 2nd and 3rd metatarsal basis, early destruction of the navicular—first cuneiform joint, and destruction of the 2nd and 3rd metatarsal phalangeal joints (Figure 2a). Her erythrocyte sedimentation rate was 55 millimeters per hour. Her right foot swelling and tenderness gradually decreased. In March of 1977 she was started on oral Penicillin VK 500 mgm. by mouth four times a day. A repeated bone scan showed persistent increased uptake in the right foot. X-rays of the right foot showed "progression of osteomyelitis" with periostitis and loss of cortical margination and joint space in the tarsal bones and at the base of the 2nd and third metatarsals. The patient did well clinically and was discharged on long-term oral Penicillin to be followed in the combined arthritis and infectious disease clinics. Her subsequent course was benign but her nontender right foot swelling persisted and her x-rays showed further destruction of the tarsus (Figure 2b). For this reason she was readmitted for open bone biopsy and for bone cultures to attempt to differentiate osteomyelitis from a diabetic neurosteoarthropathy. Her sedimentation rate on final admission was 38 millimeters per hour. Open biopsy of the tarsal bones was carried out through a dorsal incision over the medial cuneiform. Bone was obtained for histology and for culture and sensitivity as well as cultures for AFB and for aerobic and anoerobic organisms. All cultures were later reported as negative.

## Discussion

Five percent of diabetics develop peripheral neuropathy[5] not unlike the polyneuropathy of Syringomyelia, Tabes Dorsales, Syphillis, Alcoholism, Leprosy. Some patients develop a Mononeuropathy Multiplex, which is often unilateral, has a sudden onset of pain, exhibits sensory, motor, and autonomic loss in the distribution of one peripheral nerve, so that occasionally it has to be differentiated

Figure 2
Technitium 99 Polyphosphate bone scan demonstrating increased uptake in the right foot including the 2nd and 3rd metatarsals and metatarsal phalangeal joints.

from nerve root compression due to a disc herniation. The etiology of Monoeuropathy Multiplex is thought to be small infarcts of peripheral nerves caused by the occlusion of small arteries[8] resulting in bony changes frequently indistinguishable from osteomyelitis, hypertrophic osteoarthritis, tuberculosis, malignancy, and fractures. It is often initiated during a period of neglect when the diabetes is out of control, however it is known to occur in mild diabetes as well as in more severe forms. Factors such as toxic hyperthyroidism, diabetic acidosis, pneumonia and trauma can initiate or compound the process, but the factors most associated with its occurrence are pyogenic infections and altered perception of stresses applied to the foot. The prognosis for spontaneous recovery or stabilization of the osteoarthropathy in 6 to 12 months is usually good, although such was not the case in our first patient.

Nerve conduction studies[2] in mononeuropathy showed segmental demyelinization with retrograde denervation of peripheral nerve fibers ("Dying Back") involving axons of all calibers. Motor, sensory, and autonomic nerve fibers have been shown to be damaged together, separately, and/or sequentially, accounting for the variation in degree and progression of symptoms.

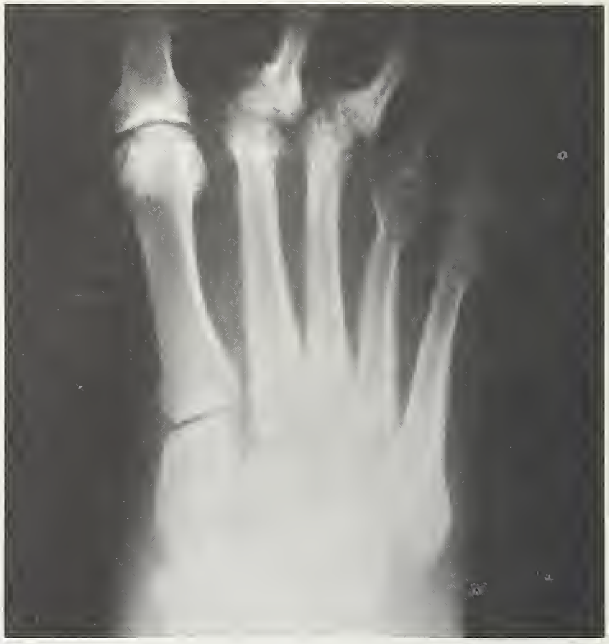

Figure 2a
Earliest antero-posterior roentgenogram of the right foot showing subluxation and destruction of the 2nd and 3rd metatarsal phalangeal joints, and early involvement of the medial aspect of the naviculo-1st cuneiform joint.

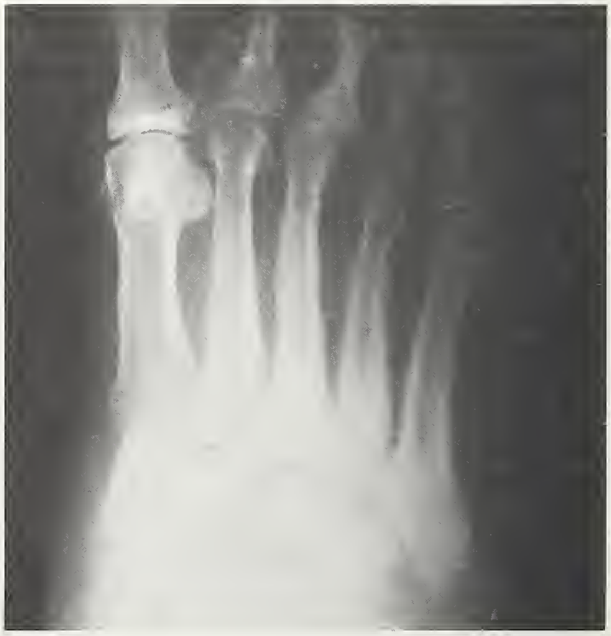

Figure 2b
Anterio-posterior roentgenograms of the right foot showing progressive healing of the 2nd and 3rd metatarsal phalangeal joints and 2nd and 3rd metatarsals, but increasing destruction of the midtarsal joints.

Motor neuropathy leads to weakness of the intrinsic muscles of the foot resulting in the intrinsic-minus deformity, i.e., pes cavus, hammer toe with extensor subluxation of the toes, concomitant plantar prominence of the metatarsal heads and proximal migration of the metatarsal fat pads.

Sensory involvement decreases perception of pain and proprioception causing repeated unchecked trauma to bones, joints, and supporting ligaments with eventual breakdown of normal bony architecture. Loss of sensitivity and persistent activity must both be present for this destructive process to take place.

The affected peripheral nerve contains sympathetic fibers which carry vasoconstricting impulses. When these fibers are damaged ("Autosympathectomy") peripheral vasodilatation results which leads to hyperemia.[9] Good circulation is a sine-qua-non for bone resorption and deposition to take place.[7] Indeed these patients have good dorsalis pedis and posterior tibial pulses. Arteriography and technitium 99 polyphosphate bone scan (Figure 2) show hypervascularization of the mid-foot indicative of hyperemia and possibly A-V Communications.[2]

The clinical appearance of the neuropathic foot follows certain patterns of destruction of the tarsal bones which may be dictated by of involvement of the medial plantar nerve[3] which supplies the plantar aspect of the tarsus and by the lateral terminal branches of the deep peroneal nerve[3] (Anterior tibial nerve) which innervates the superior and lateral tarsal joints. If the medial plantar branch is diseased one would expect that the talus, navicular and/or cuneiform will gradually disintegrate and displace downward to create a "flat foot," but the cuboid would remain relatively intact, therby preventing valgus displacement of the forefoot. Involvement of the branch of the deep peroneal nerve would more likely affect the lateral column of the foot, i.e., the calcaneous, cuboid, and the lateral cuneiforms causing a "rocker bottom" foot with valgus displacement of the forefoot.

Engineers point out that the construction of the normal foot allows the dorsal bones to act entirely as compression members of a deep lever while the tension is taken up momentarily by the cuboid, plantar fascia, and the muscles.[4] Any weakening of the plantar tensor components as from disruption of the cuboid and/or intrinsic paralysis would impose angulating forces on the bones and joints localizing compression entirely to the dorsal edges of the bones.

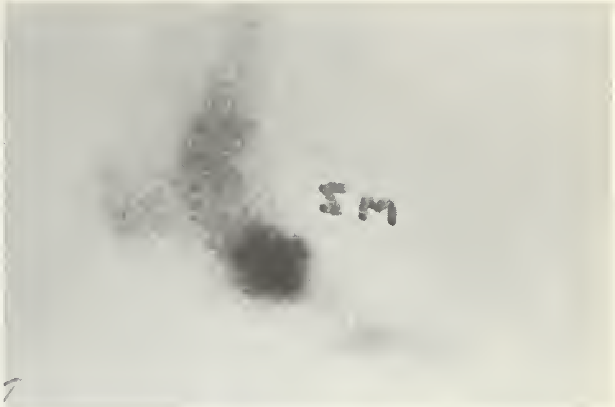

Figure 3a
Technitium 99 Polyphosphate bone scan of the right foot of case 1 showing increased uptake at mid-foot.

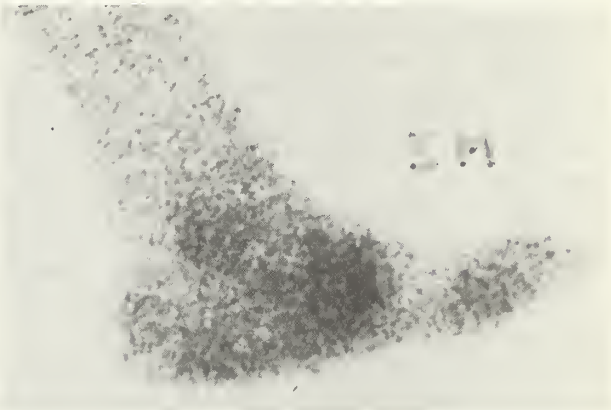

Figure 3b
Gallium Scan of the right foot of case 1 showing minimal increase in uptake compared to Figure 3a.

The importance of infection in the production and subsequent influencing of this process is recognized but its exact effect is unknown. It is thought that sepsis alone cannot account for the entire process, notice the low Gallium uptake (Figure 3b) in the presence of marked technitium 99 polyphosphate uptake (Figure 3a). Perforating ulcers as one often finds under points of pressure in the diabetic foot carry infection to bones. Sepsis itself causes hyperemia which together with the hyperemia produced by the selective autonomic denervation leads to demineralization of bones. In the metatarsal phalangeal joints these ulcers often cause slow erosive changes (atrophic arthritis) but in the mid-foot, where greater weight bearing stresses are present, they produce a relatively rapid, often catastrophic disintegration of the entire tarsus. The histopathologic process is one of repeated destruction and repair. Our biopsy specimen showed healthy appearing new bone with osteoblastic activity and no infection (Figure 4). In case #3, where a bacteremia was documented, infection certainly played a greater role. Indeed this patient exhibited radiographic evidence of periostitis of the 2nd and 3rd metatarsals indicative of a superimposed septic process. The earliest x-rays (Figure 2a) at the time of her initial admission for cellulitis show advanced destructive changes of the 2nd and 3rd metatarsal phalangeal joints but also early changes at the naviculo-first cuneiform joint. Interval films (Figure 2b) show healing of the metatarsal phalangeal joints,

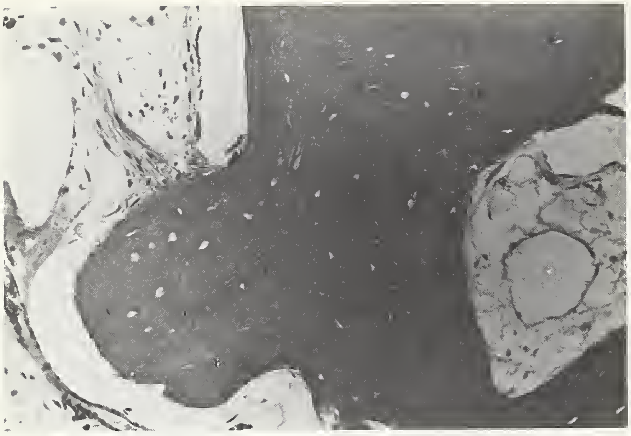

Figure 4
Photomicrograph (450 x) of biopsy specimen from the 1st naviculo-cuneiform joint from case 3 (Figure 2b), showing live young bone, osteoblastic activity, and no infection.

but progressive destruction of the tarsal bones. It is interesting to note that the metatarsal phalangeal joints responded to antibiotic treatment and their healing paralleled the gradual decrease in sedimentation rate while the tarsal changes worsened during the same time. Since all cultures and the bone biopsy from the 1st cuneiform (Figure 4) did not show a septic process, one would conclude that the tarsal destruction was due to diabetic neurosteoarthropathy and that the effect of a nearby infection on this process can only be surmised.

Only one patient (case #1) complained bitterly of severe unrelenting pain in her feet. A below knee amputation was done because of intractable pain, chronic, recurrent non-healing ulcers and recurrent bouts of cellulitis in her right foot and leg. She obtained complete relief of symptoms. She is now complaining of severe pain in the left foot for the past 14 months, but ulcers have not developed. In cases of bilateral disease when amputation is necessary, a low amputation should be performed, possibly a Symes, so that in their household these patients can ambulate brace free. Since 20 to 30% of lesions in diabetic feet are of neuropathic rather than ischemic nature[6] a leg or mid-thigh amputation in an uncomplicated neuropathic foot is seldom necessary.

The main stay of treatment should be conservative and only the most intractable cases should come to amputation.

Preventive measures should be taken to avoid skin breakdown and subsequent infection. Diabetic patients should be cared for in a Diabetic Foot Clinic where skilled care to nails and calluses can be given and early warning signs of impending trouble heeded. Self-discipline should be taught and weight reduction encouraged. Trophic ulcers should be debrided to allow reepithelialization to take place. Appropriate pressure relieving pads and shoes should be provided. Often a Harris Mat (Harris Mat: Downs Surgical Inc., 655 73rd Street, Niagara Falls, New York, 14301) can be used to determine pressure points prior to designing proper shoes. In the early stages of the neuropathic foot before collapse of the mid-foot and during the painful stage, the leg and foot can be immobilized in a well-padded, well-molded walking cast. If the medial longitudinal arch is preserved, a medial arch support made of a firm but soft material which extends up to the medial counter of the shoe should be prescribed. When the medial longitudinal arch is absent an arch support is not advisable since it tends to localize pressure and cause ulceration. The use of a rocker shoe with a SACH heel and a steel shank sole is recommended. The central rocker serves as a pivoting point and effectively enhances push-off.[4] The so-called “space shoe” is not indicated because it accommodates poorly to the changes that take place in the neuropathic foot, moreover it does not aid in push-off but may actually hinder it.

Surgical fusion can be attempted judiciously to remove bony prominences and to stabilize the foot early before total collapse. Wounds usually heal well and promptly if careful technique is observed. Success in fusing these joints has been reported in leprosy if done early and if joints are excised boldly back to normal appearing bones.[4]

Finally, the patient should learn to walk in short steps to minimize heel impact. He should learn all he can about his disease and how it affects his feet, he should heed early warning signs and keep his feet and footwear in good working order.

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# The Biological Effects of Ionizing Radiation

MARK H. BARNETT, M.P.H.

## INTRODUCTION

The fact that ionizing radiation which includes X-rays and the radiation emitted by radioactive materials, can produce biological damage has been known for many years. The first case of human injury was reported in the literature just a few months following Roentgen's original paper in 1895 announcing the discovery of x-rays. In addition to the acute, short-term effects which result from large exposures, ionizing radiation may also induce more subtle, long-term effects which do not manifest themselves until years after the original exposure. As early as 1902, the first case of x-ray induced cancer was reported in the literature.

Early human evidence of harmful effects as a result of exposure to radiation in large amounts existed in the 1920's and 30's, based upon the experience of early radiologists, miners exposed to airborne radioactivity underground, persons working in the radium industry, and other special occupational groups. The long-term biological significance of smaller, repeated doses of radiation, however, was not widely appreciated until relatively recently, and most of our knowledge of the biological effects of radiation has been accumulated since World War II.

## SEQUENTIAL PATTERN OF BIOLOGICAL EFFECTS

In general, the sequence of events following radiation exposure may be classified as follows:

### A. Latent Period

Following the initial radiation event, and before the first detectable effect occurs, there is a time lag referred to as the latent period. There is a vast time range possible in the latent period. The biological effects of radiation are arbitrarily divided into short-term and long-term effects on this basis. Those effects which appear within a matter of minutes, days, or weeks are called short-term effects and those which appear years, decades, and sometimes generations later are called long-term effects.

### B. Period of Demonstrable Effects on Cells and Tissues

During or immediately following the latent period, certain discrete effects can be observed.

One of the phenomena that is seen most frequently in growing tissues exposed to radiation is the cessation of mitosis, or cell division. This may be temporary or permanent, depending upon the radiation dosage. Other effects include breaking or clumping of chromosomes, and, formation of giant cells or other abnormal mitoses. It should be pointed out that many of these effects can be duplicated individually with other types of agents. However, the entire gamut of effects cannot be reproduced by any single chemical agent.

### C. Recovery Period

Following exposure to radiation, recovery can take place to a certain extent. This is particularly apparent in the case of the short-term effects, i.e., those appearing within a matter of days or weeks after exposure. However, there may be a residual damage from which no recovery occurs, and it is this irreparable injury which can give rise to later long-term effects.

### Threshold vs. Non-threshold

For radiation, a key question has been whether or not there exists a threshold dose, that is, a dose below which no biological response takes place. If radiation damage has no threshold, this would imply some small degree of risk no matter how low the dose. Although some radiation effects obviously do not occur until a threshold dose is reached (e.g., erythema of the skin), there is evidence that some of the effects of radiation constitute non-threshold phenomena. Hence one of the underlying (and prudent) assumptions in the establishment of radiation protection guides and in radiation control activities in public health programs has been the existence of a non-threshold effect. This means that some degree of risk exists when large populations of people are exposed to even very small amounts of radiation. This assumption often makes the establishment of guidelines for acceptable radiation exposure a complex task, since the concept of "acceptable risk" comes into play, in which the benefit to be accrued from a given

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radiation exposure must be weighed against its hazard.

### Factors Influencing Radiation Effects

In general, the more quickly a given radiation dose is administered, the greater will be the biological effect; conversely, fractionating the dose will usually produce less effect than if it were given in a single exposure. The larger the area of the body exposed, other factors being equal, the greater the overall damage to the organism.

A wide variation in susceptibility to radiation damage exists among different types of cells and tissues. In general, those cells which are rapidly dividing or have the potential for rapid division are more sensitive than those which do not divide. Also, cells which are non-differentiated are more sensitive than those which are highly specialized. The lymphocytes are considered the most radiosensitive cells in the body, followed by other white blood cells in their immature form, and immature red blood cells. Epithelial tissue is of moderately high sensitivity, whereas muscle and nerve cells generally possess low sensitivity to radiation damage.

## SHORT-TERM EFFECTS

An acute dose of radiation is one which is delivered to the body during a very short time. If the amount of radiation involved is large enough, acute doses may result in effects which can manifest themselves within a period of hours or days. When the radiation is delivered to the whole body, the signs and symptoms which comprise these short-term effects are collectively known as the acute radiation syndrome.

When the acute radiation dose is 50 rads or less, ordinary laboratory or clinical methods will show no indications of injury from whole body irradiation. A dose of 100 rads marks the usual lower limit of the *hematopoietic form* of the acute radiation syndrome; most individuals show no symptoms at this dose, although a small percentage may experience mild blood changes. At 200 rads, most persons show definite signs of injury, including fever, hemorrhage and epilation; this dose level may prove fatal to those individuals most sensitive to the effects of radiation. At 450 rads, the median lethal dose has been reached, and 50 percent of exposed individuals will succumb, generally to infection. Approximately 600 rads usually marks the beginning of the *gastrointestinal form* of the acute radiation syndrome, characterized by severe diarrhea and associated fluid loss, with very poor prognosis for all individuals involved; a fatal outcome may well be certain at 800 to 1000 rads. At considerably higher radiation doses, the rapidly fulminating *central nervous system form* of the syndrome prevails, in which the immediate cause of death is generally cardiovascular collapse.

Again, the acute radiation syndrome occurs only when a large, whole body radiation dose is received over a short period of time. Its course may vary from hours to several weeks; the duration of the syndrome is generally inversely proportional to the amount of radiation received, with rapid illness being characteristic of very high doses.

## LONG-TERM EFFECTS

Delayed radiation effects may result from previous acute, high-dose exposures or from chronic low level exposures over a period of years. From the standpoint of public health significance, the possibility of long-term effects on the large number of people receiving low, chronic exposures is cause for greater concern than the short-term radiation effects from acute exposures which involve only a few individuals.

It should be emphasized that there is no unique disease associated with the long-term effects of radiation; these effects express themselves in human populations simply as a statistical increase in the incidence of certain already-existing conditions. Because of the low normal incidence of these conditions, it is usually necessary to observe large populations of irradiated persons in order to measure this kind of increase, and employ biostatistical and epidemiologic methodology. In addition to the large numbers of people needed for human studies of long-term radiation effects, the situation is further complicated by the latent period; in some cases, a radiation-induced increase in a disease may go unrecorded unless the study is continued for many years.

It should also be noted that although it is possible to perform true experiments with animal populations, in which all factors with the exception of radiation exposure are kept identical in study populations, human data is limited to "second hand" information, accrued from populations which have been irradiated for reasons other than radiobiological information. It is often the special characteristics of irradiated human populations, e.g., the presence of some pre-existing disease, which makes for caution in drawing meaningful conclusions when these groups are compared with non-irradiated ones.

Despite the above difficulties, many epidemiologic investigations of irradiated human beings have provided convincing evidence that ionizing radiation may indeed result in an increased risk of certain diseases long after the initial exposure. This information supplements and corroborates that gained from animal experimentation which demonstrates these same effects.

Among the long-term effects thus far observed have been somatic damage, which may result in an increased incidence of cancer, embryological defects, cataracts, and lifespan shortening; and genetic mutations, which may have an adverse effect for generations after the original radiation damage.

## CARCINOGENIC EFFECTS

With proper selection of animal species and strains, and of dose, ionizing radiation may be shown to exert an almost universal carcinogenic action, resulting in tumors in a great variety of organs and tissues. Among the tentative explanations thus far proposed for the carcinogenic action of radiation are: that the radiation may activate a latent carcinogenic virus; that it may produce specific chromosomal damage associated with certain kinds of cancer; that it may produce somatic mutations in certain types of cells which can lead to uncontrolled proliferation; and, as a result of interactions with water molecules within the cells, that it can produce free radicals which are suspected of playing a key role in both cancer induction and aging.

There is human evidence that radiation may contribute to the induction of various kinds of neoplastic diseases. Some of these findings are summarized below:

a. *Radium Dial Painters.* Early in this century, when long-term radiation effects were little recognized, luminous numerals on watches and clocks were painted by hand with fine sable brushes, dipped first in the radium-containing paint and then often tipped on the lips or tongue. Young girls commonly were employed in this occupation. Years later, studies of these individuals who had ingested radium paint have disclosed an increased incidence of bone sarcomas and other malignancies, resulting from the burdens of radium which had accumulated in their bones.

b. *Radiologists and Dentists.* Some early medical and dental users of x-rays, largely unaware of the hazards involved, accumulated considerable doses of radiation. As early as the year 1910, there were reports of cancer deaths among physicians, presumably attributable to x-ray exposure. Skin cancer was a notable finding among these early practitioners; dentists, for example, developed lesions on the fingers with which they repeatedly held dental films in their patients' mouths.

Of course, the excesses associated with the very early use of x-rays have diminished. Nonetheless, a more recent study comparing radiologists of various ages with physicians who do not use x-rays has shown that some groups of radiologists have a significantly higher incidence of leukemia than their non-radiologist counterparts. This difference seems to be largely confined to older radiologists who presumably received much of their exposure in the 1930's through 1950's when protective measures were not as widely employed as they are today.

c. *Uranium Miners.* Early in this century, certain large mines in Europe were worked for pitchblende, a uranium ore. Lung cancer was highly prevalent among the miners as a result of the inhalation of large quantities of airborne radioactive materials. It was estimated that the risk of lung cancer in the pitchblende miners was at least 50 percent higher than that of the general population.

Modern mining conditions have greatly improved. Nonetheless, recent studies have indicated a slight but statistically significant excess risk of lung cancer even among contemporary American uranium miners.

d. *Atomic Bomb Survivors.* One of the strongest supports for the concept that radiation is a leukemogenic agent in man comes from the epidemiologic studies of the survivors of the atomic bombing of Hiroshima. Survivors exposed to radiation above an estimated dose of approximately 100 rem showed a significant increase in the incidence of leukemia. In addition, leukemia incidence correlated well with the estimated dose, thus strengthening the hypothesis that the excess leukemia cases were indeed attributable to the radiation exposure. Thyroid and breast cancers have also shown an increase among the heavily irradiated survivors. The latent period for these cancers appears to have been longer than that for the radiation-induced leukemias, ranging from approximately 10 to more than 20 years.

e. *Ankylosing Spondylitis Patients.* Ankylosing spondylitis, a progressively disabling arthritic disease of the spine, has been treated with large x-ray doses delivered to the vertebrae to slow the progress of the disease and to relieve its symptoms. Persons thus treated accumulated large doses of radiation to the bone marrow. A study of a large population of such persons revealed a much higher incidence of leukemia than might be expected in the general population. It is generally agreed that radiation received by these patients was a major factor in producing the excess leukemias. However, since a control group of spondylitis patients who had not been treated with x-rays was not available for comparison in the study, it is possible that a part of the observed increase in leukemia might have been caused by (a) a possible predisposition to leukemia on the part of ankylosing spondylitis patients, and/or, (b) a possible carcinogenic effect from the drug therapy which the patients may have received along with the x-ray treatments.

f. *Children Irradiated for Thymus Enlargement.* Many young children with respiratory distress were diagnosed in former years as having enlarged thymus glands and were treated with therapeutic doses of x-rays to the thymic region. A number of follow-up studies were performed on these children, and although results varied, it is generally agreed that these persons have experienced a significantly increased incidence of thyroid cancer and other malignancies of the head and neck. Such findings are not limited to thymic irradiation; further studies have demonstrated excess thyroid cancers and other head and neck malignancies as a result of childhood irradiation to this area of the body for the treatment of wide variety of benign conditions such as enlarged tonsils and adenoids, acne, etc.

g. *Tinea Capitis Patients.* X-ray epilation was a widely used treatment for children with tinea capitis (ringworm of the scalp). A study of a group of such children in New York City, and a similar investigation in Israel, indicate an increased incidence of thyroid cancer and leukemia in the irradiated children, as well as the possibility of functional changes in the central nervous system.

h. *Patients Receiving Breast Irradiation.* A link between high doses of radiation to the chest and breast cancer was discovered in a survey of women who had been treated for tuberculosis by artificial pneumothorax, a procedure which consisted of intentionally collapsing the affected lung for a period of time and then reinflating it. This was accomplished with the assistance of the fluoroscope, and in many cases the pneumothorax treatment was repeated, sometimes more than 100 times. The patient was often positioned in the vertical fluoroscope machine facing the x-ray tube, so that the largest radiation dose was delivered to the anterior surface of the chest. The incidence of breast cancer among these heavily irradiated patients was found to be 4 to 8 times the expected rate for this disease. Further, the investigators were able to show a correlation between the side of the chest receiving the treatment and the affected breast. A similar increase in breast cancer incidence was found in a group of women who had received x-ray treatment of the breast for postpartum mastitis.

i. *Children Whose Mothers Were Irradiated During Pregnancy.* A pioneering study in this area purported to show an increased risk of leukemia among young children if they had been irradiated in utero as a result of pelvic x-ray examination of the mother. Mothers of leukemic children were questioned as to their radiation histories during pregnancy with the child in question, and these responses were compared with those of a control group, consisting of mothers of healthy playmates of the leukemic children. Originally this work received much criticism, based partly on the questionnaire technique used to elicit the information concerning radiation history. It was believed that differences in recall between the two groups of mothers might have biased the results. A larger subsequent study designed to correct for the objections to the first one corroborated its essential findings.

It should be noted that the investigations presented thus far which demonstrate the carcinogenic properties of radiation involve large doses, such as those received in therapeutic x-ray procedures, with the exception of these childhood leukemia investigations. Here, doses of radiation are low, in the diagnostic radiographic range. Such findings bear out the high sensitivity of embryonic tissues to radiation damage.

## Significance of Human Studies on Radiation Carcinogenesis

(a) In evaluating human studies of the kind described above, two important concepts should be borne in mind. Because the studies were not designed as radiobiological experiments in which all factors are held constant with the exception of radiation exposure, caution is required before the association between radiation and some later disease can be labeled as a cause-effect relationship. This is particularly true when the study group consists of patients irradiated for some disease or abnormality, since the question arises as to whether the abnormality itself might not account for the later disease rather than the irradiation. Sometimes further studies or the selection of a proper control group with which to compare the irradiated subjects can help to resolve these doubts. For example, in the spondylitis investigation, a valid question arose as to whether the disease itself might predispose the patient to develop leukemia later. A followup study which ascertained the leukemia incidence among non-irradiated rheumatic patients, helped to answer this question. Doubts concerning the studies of children with thymic irradiation could have been forestalled, had the control group consisted of children with diagnosed thymic enlargement who had not been treated with x-rays. It was not possible, however, to select such a control group; instead healthy siblings or cancer incidence from general population statistics were employed. Thus, although the weight of evidence in these studies points toward true radiation carcinogenesis, there is room for speculation as to whether the infants with enlarged thymus glands might not have been at least somewhat predisposed to the development of malignant diseases. Even the studies of the relationship of prenatal x-ray examinations to childhood leukemias have been subject to the same kind of question, e.g., whether the special characteristics of the mothers and children in question which necessitated the pelvic x-rays in the first place might not be a predisposing factor in the development of leukemia, irrespective of, or in addition to, the radiation received. Despite these reservations, all of the above studies, when taken together, comprise an impressive accumulation of evidence indicating that ionizing radiation is a true carcinogen in man.

(b) Assuming that studies such as these are valid, the question arises as to their practical implications. Even in investigations such as the spondylitis studies in which roughly a ten-fold increase in leukemia was observed, the additional risk to an irradiated individual remains small because of the relatively low normal incidence of leukemia. The small but real increase in risk to the individual calls for an intelligent balancing in each case of the benefits to be accrued from the radiation exposure and the concomitant hazard. Valuable therapeutic and diagnostic x-ray techniques which are of great benefit to patients cannot be abandoned because of the risk of delayed harmful effects; on the other hand, if the same diagnostic information or therapeutic results can be obtained using techniques which reduce radiation exposure to the patient, or if equally effective non-radiologic procedures which do not involve such risk are available, such methods should be used.

## EMBRYOLOGICAL EFFECTS

Considering the fact that immature, undifferentiated and rapidly dividing cells are highly sensitive to radiation, it is not surprising that embryonic and fetal tissues are readily damaged by relatively low doses of radiation. It has been shown in experiments with mice that deleterious effects may be produced with doses of only 10 rads delivered to the embryo during the period of organogenesis. There is no reason to doubt that the human embryo is equally susceptible. It should be emphasized that radiation is not unique in producing embryological effects and that a growing body of evidence exists which indicates that a host of external insults, including certain drugs, chemicals, and viral infections also can damage the highly sensitive embryo and fetus.

### 1. Embryological Effect vs. Stage of Pregnancy

The majority of the anomalies which are produced by prenatal irradiation involve the central nervous system, although the specific type of damage is related to the dose and to the stage of pregnancy during which irradiation takes place. In terms of embryonic death, the very earliest stages of gestation, perhaps the first few weeks of pregnancy in the human being, are most radiosensitive.

For the production of congenital anomalies in the newborn, irradiation during the period of organogenesis is of greatest importance. This period occurs during approximately the second through the sixth week of human gestation, when pregnancy could still be unsuspected. During this period, embryonic death is less likely than in the extremely early stage, but the production of morphological defects in the newborn is the major consideration.

During later stages of pregnancy, fetal tissue is more resistant to gross and easily observable damage. However, functional changes, particularly those involving the central nervous system, may result from such late exposures and would be difficult to measure or evaluate at birth. They usually involve subtle alterations in such phenomena as learning patterns and development and may have a considerable latent period before they manifest themselves. There is some evidence that the decreasing sensitivity of the fetus to gross radiation damage as pregnancy progresses may not apply for the leukemogenic effects of prenatal irradiation. Another important factor to be considered is evaluating the radiation hazard during late pregnancy is that irradiation may produce true genetic mutations in the immature germ cells of the fetus for which no threshold dose has been established.

### 2. Human Evidence for Embryological Effects

Human evidence for embryological damage has been found among persons exposed in utero at the time of the atomic bombing of Hiroshima. Data obtained from their followup through childhood and adolescence into adulthood, in which groups exposed during gestation were compared with each other and with non-exposed controls on the basis of distance from the detonation and stage of pregnancy, shows a growth stunting effect among the exposed, particularly with regard to head size, and an increased incidence of mental retardation. The risk of these developmental defects correlates well with proximity to the bomb and thus with estimated dose; also, the results further corroborate the increased sensitivity to embryological damage during the first trimester of pregnancy.

### 3. The Problem of Unsuspected Pregnancy

The increased susceptibility to radiation damage during very early gestation, when pregnancy may still not be apparent, underscores the importance of taking possible pregnancy status into account when a physician is considering pelvic, abdominal or lower back x-rays for a woman of childbearing age. It is important to ascertain whether she is or may be pregnant, and to take this information into account in deciding on the necessity of the x-ray examination.

## CATARACTOGENIC EFFECTS

Radiation in sufficiently high doses can induce cataracts in the lens of the eye. The required dose for humans, which is difficult to ascertain, probably is in the order of many hundreds of rads for x or gamma rays, and somewhat less than this for neutron irradiation. Doses of this magnitude are not received by the eye under normal conditions from either occupational or medical diagnostic exposure.

## LIFESPAN SHORTENING

In a number of animal experiments, repeated large doses of radiation have been demonstrated to have a lifespan shortening effect. The aging process per se is complex and largely obscure, and the exact mechanisms involved in this effect are as yet uncertain. Irradiated animals in these investigations appear to die of the same diseases as the non-irradiated control animals, but they do so at an earlier age. How much of the total effect is due to premature aging and how much to an increased incidence of radiation-induced diseases is still unresolved.

## GENETIC EFFECTS

A large number of agents have mutagenic properties, and it is probable that our current knowledge includes just a fraction of these. Among the various external influences which have been found to be mutagenic are a wide variety of chemicals, certain drugs, and physical factors such as elevated temperatures and ionizing radiation. Natural background radiation probably accounts for a small proportion of naturally occurring mutations. For man, it has been estimated that background radiation probably produces less than ten percent of these. Manmade radiation, of course, if delivered to the gonads, can also produce mutations, over and above those which occur spontaneously. Radiation, it should be noted, is not unique in this respect, and is probably one of a number of manmade environmental influences that is capable of increasing the mutation rate.

Measuring changes in the normal mutation rate in humans is extremely difficult for several reasons. First, the majority of mutations are recessive, that is, their full effects do not manifest themselves in an individual unless he or she carries the same mutational defect in the same location on a given pair of chromosomes, i.e., unless both the mother and father were afflicted with the same kind of genetic damage. It can be seen from this that it might take many generations after a genetically damaging event occurred in a population before enough individuals carrying the recessive mutation mated with one another to produce offspring who would demonstrate overt damage. Secondly, contrary to popular impression, the damage produced by most mutations is subtle in its effects and difficult to measure. Mutations, for example, may result in a slightly altered metabolism, in which there is a less efficient utilization of certain nutritional elements, or a slightly greater predisposition to a given disease, or a slightly lower intelligence than would otherwise have been attained. Adding to this is the difficulty encountered in extricating true genetic phenomena from other influences which may produce the same results. It would be most difficult, for example, to determine whether an individual's predisposition to heart disease were due to a subtle genetic defect in his cardiovascular system, or to environmental stresses such as diet or occupation, or to personality and developmental factors in childhood, etc. For these reasons, most of the evidence concerning the genetic effects of ionizing radiation is derived from animal experiments.

The mutagenic properties of ionizing radiation were first discovered in 1927, using the fruit fly as the experimental animal. Since that time, experiments have been extended to include other species, and a great deal of recent investigation has been carried out on the mouse. Animal experimentation remains our chief source of information concerning the genetic effects of radiation, and as a result of the intensive experimentation which has been carried out during recent years, certain generalizations may be made. Among those of health significance are (1) that there is no indication of a threshold dose for the genetic effects of radiation, i.e., a dose below which genetic damage does not occur, and (2) that the degree of mutational damage which results from radiation exposure seems to be dose-rate dependent, so that a given dose is less effective in producing damage if it is protracted or fractionated over a long period of time.

With contemporary human populations, it is highly desirable to keep the level of the mutational pool as low as possible, since the pool largely represents diseases and defects which tend to lower overall biological fitness. However, two factors unique to modern life may tend to increase the level. First, human populations are being exposed to a greater and greater number of potential mutagens as a result of a progressive increase in the variety and quantity of manmade chemical and physical agents which are a product of our technological advances. Secondly, modern medical knowledge and techniques result in the salvage of more and more individuals with genetic defects so that they may reproduce themselves, thus distributing these defects to an ever larger number of people. In the face of these factors which tend to increase the mutational load in the world's population, it is all the more important, if the level of the pool is to be kept at a minimum, to make every effort to maintain the influx of new mutations as small as possible. Considering the potent mutagenic properties of ionizing radiation, the goal, then, is clear: to avoid any unnecessary irradiation of the gonads.

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# Occupational Medicine

RAYMOND A. YERG, M.D.

Occupational medicine may be defined as: A subspecialty field of preventive medicine concerned with: (1) the appraisal, maintenance, restoration, and improvement of the health of the worker through application of principles of preventive medicine, emergency medical care, rehabilitation, and environmental medicine; (2) the promotion of a productive and fulfilling interaction of the worker with his work, through the application of principles of human behavior; (3) the active appreciation of the social, economic, and administrative needs and responsibilities of both the worker and the work community; and (4) a health and safety team approach involving cooperation of the physician with occupational hygienists, occupational nurses, safety personnel and toxicologists.

The Occupational Safety and Health Act of 1970 has recently highlighted many actual and potential health problems in the workplace. Substances and materials, previously thought to be innocuous or without harm to workers, are now being found to have toxic properties. Management's responsibility to provide an optimal health environment for the worker places a further responsibility on physicians to initiate programs for prevention and control of occupational illness. This implies that practicing physicians involved in primary patient care must maintain an awareness of potential work-related illness—not only to insure proper treatment but also to play an active role in prevention programs.

In the diagnosis of occupationally related diseases, five factors are of critical importance:

1. An initial index of suspicion,
2. A meticulous and detailed occupational history,
3. Knowledge of the nature, severity and duration of the exposure,
4. Signs and symptoms consistent with the toxicity of the material to which exposed, and finally
5. Supporting clinical and laboratory tests to confirm the diagnosis.

A most valuable reference for the practicing physician is entitled: "Occupational Diseases, A Guide to their Recognition." This book, revised in June, 1977, published by the U.S. Department of Health, Education and Welfare, is available from the Superintendent of Documents, Government Printing Office, Washington, D.C.

The text covers such things as routes of entry and modes of action, chemical, biological and physical hazards, dermatoses, pulmonary disorders, plant and wood hazards, chemical carcinogens, pesticides, sources of consultation and a list of references.

Another recent text is "Occupational Medicine—Principles and Practical Application" edited by Carl Zenz, M.D., ScD., Year Book Medical Publishers.

In the State of Connecticut, South Western Fairfield County is rapidly becoming the commercial industrial center of the State. Twenty-three of the top 500 industrial companies listed in Fortune's, May 1977 issue, now have their Corporate headquarters in the Stamford or Norwalk areas. This concentration of manufacturing headquarters activity in the State of Connecticut places additional burdens on the medical community to be increasingly involved in the routine health care and occupational health of the employees of these companies.

Historically, it was in 1959 that Dr. John Wister Meigs, now Clinical Professor at Yale University, then Chairman of the State Committee on Industrial Health, gathered a group of physicians to meet periodically and discuss subjects of mutual interest in occupational medicine.

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Dr. Yerg holds a Master's Degree in Public Health from Harvard and is Board Certified in Preventive Medicine, Aviation Medicine and Occupational Medicine.

The Occupational Medical Association of Connecticut was formally established on the 16th day of January, 1963, when it was split off from the New England Industrial Medical Association. It is a full participating component of the American Occupational Medical Association.

The Association now has 84 active members, 22 of whom are Certified by the American Board of Preventive Medicine in the specialty of occupational medicine.

The Occupational Medical Association of Connecticut has as its OBJECT:

> "to foster the practice of occupational medicine in the State of Connecticut under the laws and occupational conditions peculiar to this state. The association shall unite in one organization all physicians who are interested in promulgating acceptable health practices, and in developing new methods and ideas for the maintenance of good health among industrial workers. A major object of the association shall be the promotion of an understanding of preventive and occupational medicine within the medical profession and among the lay public."

Recently, the American Occupational Medical Association adopted a Code of Ethical Conduct for Physicians providing occupational medical services. This 12 point code affirmed the organization's advocacy of "unbiased medical judgment above all other considerations and loyalties." The code was developed by a committee headed by Norbert J. Roberts, M.D., Medical Director, Exxon Corporation. Other members include Thomas S. Ely, M.D., Assistant Director, Health and Safety Laboratory, Eastman Kodak Company; Robert S. Hockwald, M.D., Medical Director, Pacific Telephone Company; Eugene H. Kremmer, III, M.D., private practitioner; William E. Morton, M.D., Professor, University of Oregon Medical School; Bernard J. Schuman, M.D., Medical Director, Port Authority of New York and New Jersey; and Irving Tabershaw, M.D., consultant in occupational medicine.

The Code is reproduced here in its entirety:

- "Accord the highest priority to the health and safety of the individual in the workplace.
- Practice on a scientific basis with objectivity and integrity.
- Make or endorse only statements which reflect their observations or honest opinion.
- Actively oppose and strive to correct unethical conduct in relation to occupational health service.
- Avoid allowing their medical judgment to be influenced by any conflict of interest.
- Strive conscientiously to become familiar with the medical fitness requirements, the environment and the hazards of the work done by those they serve, and with the health aspects of the products and operations involved.
- Treat as confidential whatever is learned about individuals served, releasing information only when required by law or by over-riding public health considerations, or to other physicians at the request of the individual according to traditional medical ethical practice; and should recognize that employers are entitled to counsel about the medical fitness of individuals in relation to work, but are not entitled to diagnoses or details of a specific nature.
- Strive continually to improve medical knowledge, and should communicate information about health hazards in timely and effective fashion to individuals or groups potentially affected, and make appropriate reports to the scientific community.
- Communicate understandably to those they serve any significant observations about their health, recommending further study, counsel or treatment when indicated.
- Seek consultation concerning the individual or the workplace whenever indicated.
- Cooperate with governmental health personnel and agencies, and foster and maintain sound ethical relationships with other members of the health professions.
- Avoid solicitation of the use of their services by making claims, offering testimonials, or implying results which may not be achieved, but they may appropriately advise colleagues and others of services available."

Recently, the American Medical Association's Judicial Council provided Guidelines on the Confidentiality of Pre-placement and Pre-employment health examinations. This question is frequently raised with respect to the release of medical information unless it is required by law or is necessary to protect the welfare of the individual or the community. The Judicial Council Report is reproduced here in its entirety as a guideline for practicing physicians in the State of Connecticut.

> "A physician has an obligation to keep secret information about a patient that is obtained in the course of his professional employment. Information in a medical record or report is confidential and should not be communicated to a third party without the patient's prior written consent, unless it is required by law or is necessary to protect the welfare of the individual or the community.
>
> "At the same time, patients may have legitimate desires to have medical records concerning their care and treatment forwarded to others. This may typically occur in a clinic or private office practice that conducts a physical examination and takes the history of a patient for release to the patient's prospective employer.

"In the normal course of events, the release of such information should not present a problem if the patient's consent is appropriately obtained. In some instances, however, the patient may wish to have certain relevant information withheld from the physician's report on the employment examination and history. The patient may not want certain prior or current medical information reported as it may impede the patient's chance to obtain the job.

"In this latter instance, the examining physician has been put in an awkward and unfair position. If he fails to disclose the relevant information, he will be untruthful; but if he does disclose the information, the patient will be unhappy. The patient has come for an examination to disclose relevant information to a prospective employer, but the patient wants certain relevant information kept secret from the prospective employer. The physician is thus furtively asked to fail to perform the service that has been formally requested by all involved.

"In this situation, the responsible physician should either provide the service formally requested or refuse to make the examination and report. The best, and possibly the only, way to prevent problems in these situations would be to have the patient sign a form authorizing the release of all relevant information to the employer requesting it, following an explanation by the physician to the patient of the medical responsibilities involved. This practice should eliminate misunderstandings and an impossible choice between potentially conflicting professional and personal alternatives. This practice should also fulfill the patient's rightful expectations of both confidentiality and authorized release of appropriate information for legitimate purposes."

It is planned that other articles relating to occupational medicine, will be published in the near future in Connecticut Medicine, on the following subjects:

- Carcinogens in the work place.
- Medical surveillance requirements of occupational health standards.
- Medical aspects of Workers Compensation, etc.

Information about membership in the Occupational Medical Association of Connecticut can be obtained from the Secretary, Dr. J. Dexter Forbes, Corporate Medical Director, Uniroyal, Inc., Oxford Management & Research Center, Middlebury, Connecticut 06749. Physicians who have questions or who need assistance from Board Certified Specialists in the practice of occupational medicine, may obtain help by calling the Secretary (203-573-2136) or by contacting the American Occupational Medical Association in Chicago, Illinois. Many useful pamphlets and books are available from the association. In addition, a monthly journal is published, entitled: "Occupational Medicine."

If you are a parttime or fulltime physician in Connecticut with responsibilities in the field of employee or occupational health your input is needed and you and your organization or company stand to benefit from membership in the Occupational Medical Association of Connecticut.

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## Malpractice Problem in Europe

France and West Germany are experiencing a great increase in the number of malpractice suits. The cause for this rapid growth of malpractice cases is being investigated. One reason may be that the public is overly aware of the possibility of suing the physician and making money, which has been publicized by the news media from the western hemisphere.

When discussing the medical malpractice situation, the West German lay press often emphasizes that medical care in West Germany is widely available and that the quality of care is of the highest caliber in the world. The newspapers indicate that the reason for this rapid increase in malpractice suits is due to the attitudes of patients, as well as of all those who are involved in handling such suits. *Westfalische Nachrichten* (Feb. 8, 1978) claims that up to the present fewer than 15% of all medical malpractice suits were based on reasonable grounds. The majority of suits were either without evidence of wrongdoing on the part of the physicians or nuisance or revenge-type claims.

— JAMA, May 5, 1978

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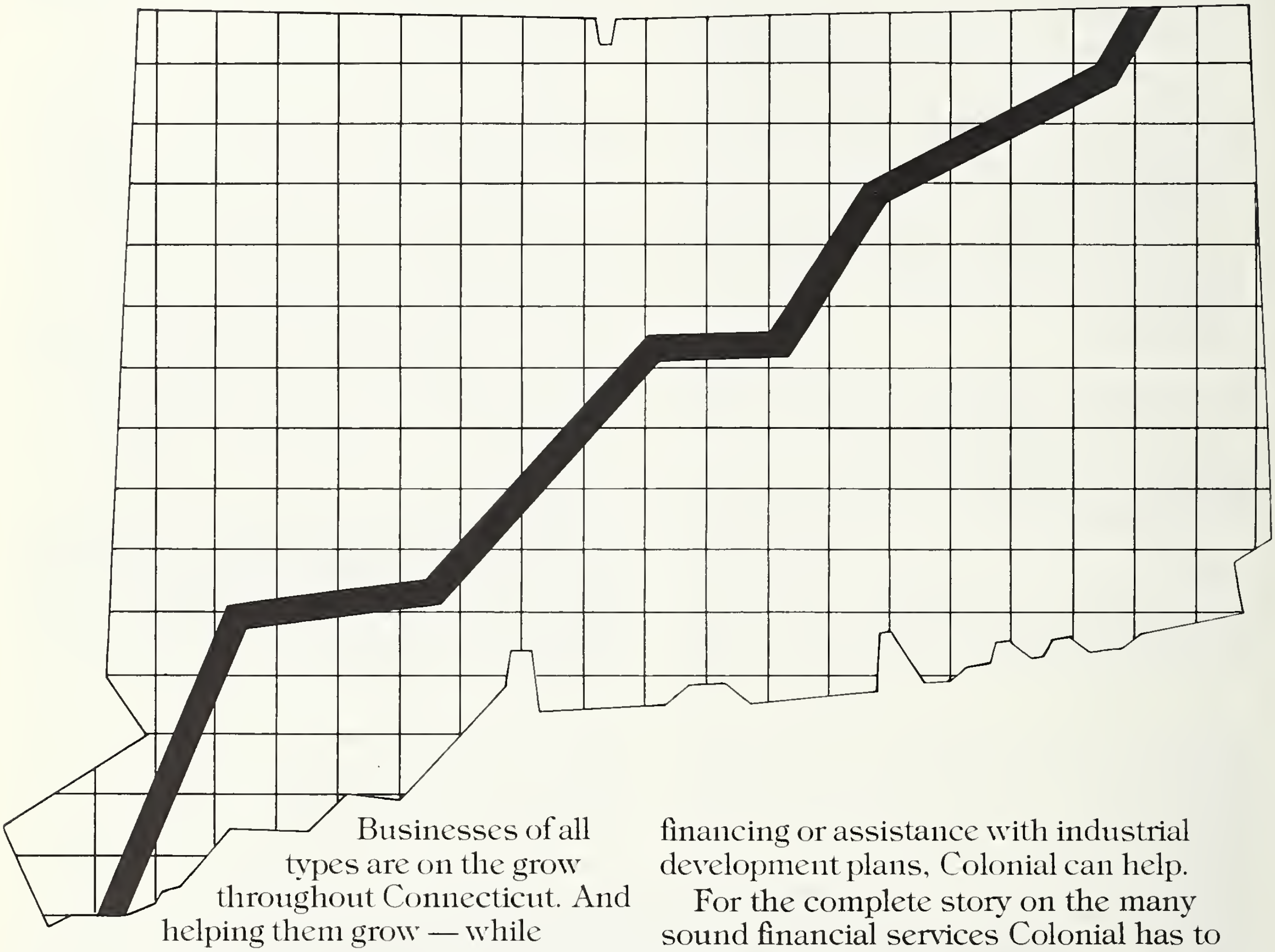

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# The Question Is . . .

## ADDRESS OF TOM E. NESBITT, M.D.
## PRESIDENT OF THE AMA

I flew into Chicago last Tuesday with my mid-year message to this House of Delegates well in hand.

But less than 24 hours later, the ruling against the AMA by a Federal Trade Commission judge was made public.

To reiterate, the substance of this ruling is that the Association, as well as the Connecticut State Medical Society and the New Haven County Medical Association, have restrained physician advertising; and restrained physician participation in other health care delivery systems.

Furthermore, this ruling—if approved by the FTC—would prohibit the AMA from establishing ethical guidelines in certain areas without first securing permission from the FTC; cast the AMA in the role of federal informer for any possible violations of the ruling by state or county medical societies; and compel the AMA to become a policeman for the FTC in enforcing provisions of the ruling.

What, then, is the response of your elected leadership to this ruling? Well, now hear this solemn promise:

We intend to employ every weapon at our command, legal or legislative, to fight this ruling.

If necessary, we'll take our case to the Supreme Court.

We intend to fight because the AMA is a private, voluntary association, and not an involutary extension of the FTC.

We intend to fight because state and local medical societies are free and independent organizations over which the AMA has not, does not, and should not, have authority.

We intend to fight because of the timeless and irrevocable oath that all reputable physicians observe, the oath that says, first, we must do no harm—such as the injury and death that have resulted from the unscrupulous public solicitation of patients for some abortion mills here in Chicago; as well as from the misleading solicitation of patients for cosmetic surgery in California, Florida, and elsewhere.

We intend to fight because it is false and misleading advertising, and not straightforward advertising by reputable physicians, that the AMA opposes.

We intend to fight because as recently as last June, when this House met in St. Louis, our Association supported continued experimentation with alternate mechanisms for the delivery of medical care.

And finally, we intend to fight because of another alarming implication.

I mean if medicine must accept the federal government as the final arbiter of the ethical conduct of the profession and its practitioners, what about other professions and institutions in our society, such as the news media, charitable organizations, and perhaps even state and local governments and their agencies?

Should the federal government be the final judge for the ethical conduct of just about every citizen? I think there are three answers to that question.

NO! NO! And NO!

But you know, there is a larger and more critical question now before this House of Delegates—one which must be answered before we adjourn on Wednesday. We intend to fight the ruling by the FTC judge tooth and nail.

But the question is: Will we be able to?

We may not be able to do so, you see, especially if we ourselves become our own worst enemies by risking professional suicide over the issue of chiropractic.

Now make no mistake about it. If we do become

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TOM E. NESBITT, M.D., of Nashville, Tenn., AMA's 133rd president, delivered this address at the Interim Meeting of the AMA House of Delegates, December 3, 1978, Chicago, Illinois.

hopelessly divided over the chiropractic dispute; if we do leave this Winter Meeting in dangerous disarray; then it will be tantamount to professional suicide.

Even worse, it would be a needless sacrifice. Because when you strip the chiropractic dispute of its emotional overtones, you find:

—That the AMA's basic position that chiropractic is an unscientific discipline is not at issue in the Pennsylvania and New Jersey litigation;

—That this position is at issue in the Chicago litigation, which is where we will take our legal stand; that chiropractors, as individuals, are licensed in all 50 states, a hard fact that cannot be ignored by anyone, including the AMA.

—And that the agreed-upon settlement in the Pennsylvania case simply states that "specialists, including those in radiology or clinical pathology, ethically may choose either to accept or to decline patients sent to them" by chiropractors.

This conforms to our Principles of Medical Ethics which specify that "a physician may choose whom he will serve."

But this freedom of choice would be conspiracy if we collectively agreed to make the same choice, which is what the specialty societies involved would have us do in Pennsylvania and New Jersey.

This would clearly be illegal. Worse yet, the penalties exacted would result in a crippling blow to everything that the AMA is, and means, to American medicine.

Consider our continuing contributions to the preeminence of our medical schools, and the excellence of our graduate and specialty training programs.

The beneficial fruits of these commitments are not hard to find. In just five years, between 1971 and 1976, the number of accredited medical schools increased from 103 to 116; the number of medical graduates from 9,000 to more than 13,000; and the total number of physicians increased from 359,000 to 425,000.

In the coming year we want to maintain the AMA's commitments to the superb quality of American medical education and practice.

The question is: Will we be able to?

What about the significant and heartening progress we have made within the past year in coping with the problem that tops everyone's medical care hit list—rising medical costs.

The evidence of that progress is not hard to find. Acting in concert with the American Hospital Association and the Federation of American Hospitals, we not only met, but surpassed, the basic goal of the Voluntary Effort.

This goal, of course, is to reduce the rate of increase in hospital expenditures by two percentage points a year. And, by August 1st, this rate of increase had been reduced by three percentage points, down to about 13 per cent, as compared with the 1977 increase of about 16 per cent.

We achieved this success because thousands of individual health professionals across the country voluntarily joined us in the Voluntary Effort.

Within the past year alone, more than 40 per cent of the nation's 7,000-plus hospitals have been certified as cost-containment institutions.

More than 45 states have established provisional cost-containment certification programs, while at least 8 states have adopted their own numerical goals to reduce medical costs.

Meanwhile, within the past few months, a number of medical organizations—including state and local medical societies—have endorsed the Voluntary Effort, and in some cases my own request that individual physicians voluntarily restrain annual increases in their own professional fees. To cite some examples, endorsements by state medical societies include those from New Jersey, Virginia, Kentucky, Missouri, Colorado, Utah and Washington State.

And all this is not to mention support from various medical schools and specialty societies, as well as housestaff physicians and medical students.

In addition, your AMA officers carried the message for responsive but responsible solutions to today's medical problems—notably cost problems—far and wide.

We carried the message to millions of Americans, through the recent advertising campaign that focused partly on what the public itself can do to reduce medical costs.

We carried the message to 30 leading newspapers, in face-to-face discussions with editorial representatives, as well as to three major news magazines and several nationally-syndicated columnists.

And we carried the message to the top executive teams on 37 of America's largest corporations. Following one such visit, I received a letter from the president of a large corporation, a letter which serves as an unsolicited testament to the effectiveness of our Media and Corporate Visitation Programs.

The letter says, in part, "Your rounds of meetings with the national press, corporations, labor and government representatives clearly show that the AMA is communicating in a way that it has never done before."

We also recognize, of course, that physicians, as keepers of the medical gates, have a particularly heavy responsibility in the quest to moderate costs. Hence we have attempted to provide individual physicians with the tools necessary to the task.

We have made available existing tools, such as the AMA cost-containment checklist for individual physicians, appropriate materials from the AMA cost-containment kit distributed to state and local medical societies, which is not to mention similar materials being provided by state and local medical societies themselves.

We also are fashioning new tools, such as the collection of precise data on cost containment, so that we can more precisely measure economies we know have been achieved by individual physicians, and by our collective voluntary efforts.

I should add that this will include any additional efforts directed by this House of Delegates in the wake of the 48 recommendations of the National Commission on the Cost of Medical Care.

During the coming year, we hope to continue our communication, and our commitments, in voluntary cost cost containment.

We hope to persuade individual physicians to look hard at their own offices, at their own clinics, and at their own hospitals.

We want to remind them that even the smallest economies, when multiplied manyfold, will add up to millions—and ultimately billions—of dollars in savings.

We want to remind them they are being asked to do no less than what physicians have always done, which is to affirm the public's abiding faith in us. Such are the cost-containment goals we hope to meet in the coming year.

The question is: Will we be able to?

Finally, there is the abundant evidence of the AMA's success in helping to ward off potentially-damaging federal legislation during the last session of the Congress.

Not enacted was the Califano and Company proposal to slap an arbitrary, 9 per cent ceiling on the annual expenditure increases for all hospitals, thereby punishing the efficient along with the inefficient.

Not enacted was the Drug Regulation and Reform Bill, which would have further confounded the development, distribution, and use of beneficial new drugs.

Not enacted was the proposal to federally license and regulate clinical laboratories intra-state, a proposal we objected to primarily because it would have extended into the laboratories in many physicians' offices.

And not enacted were amendments to the 1974 Health Planning Act, including those that would have injected Certificate of Need provisions into physicians' offices.

Now it's obvious to me, as I think it is to you, that the legislative measures I have mentioned, plus numerous others that I haven't mentioned, are almost sure to reappear in the new Congress.

Certainly the meat-axe approach to hospital cost containment—ala Califano—is sure to reappear, as are various proposals for national health insurance. And the upcoming NHI debate poses another question for us.

Will the AMA continue to be up front with the American people, with an NHI proposal of our own (a proposal which, in actuality, intent and purpose, is a "health insurance improvement plan"?) or will be reduced to the role of a mere NHI critic—and a backseat critic at that?

Well, I can only close these remarks with the following observations:

As a former Delegate to, and Speaker of, this House, I am fully confident that your answers to the questions I have posed will be the right answers. As a physician, too, I believe your answers will be the right ones.

Because the faith that patients have in us as physicians and the faith that the public has in our profession and in this federation, will be worth exactly nothing unless we demonstrate—conclusively demonstrate—that we have faith in ourselves.

And the question is, come next Wednesday:

Will we be able to?

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# Child Abuse and Neglect: The Physician's Role in Diagnosis and Reporting

(First of Three Parts)

DAVID L. KERNS, M.D.

**ABSTRACT—The Connecticut physician working with children and families is being increasingly called upon to make diagnostic and dispositional decisions in child abuse and neglect cases. This paper presents diagnostic criteria, particularly in regard to physical abuse, sexual mistreatment and failure-to-thrive secondary to nutritional neglect. The relevant portions of the Connecticut Child Protection Statutes are reviewed and the significant obstacles to physician involvement in these cases are discussed.**

With the ever increasing public and professional awareness and reporting of child abuse and neglect[1] has come the necessity for physicians to not only refine their diagnostic skills, but to respond to specific legal mandates and participate in community human service systems that are unique to this widespread problem. This paper will focus on the physician's role in the identification of child abuse and neglect and the subsequent legal responsibilities as mandated by the Connecticut Child Protection Statutes.[2]

### The Spectrum of Child Abuse and Neglect

"Child abuse and neglect," used here interchangeably with "maltreatment," refers to a spectrum of caretaker commissions and omissions which includes physical abuse, sexual molestation, emotional abuse, deprivation of food and shelter, educational and medical care neglect, emotional neglect, lack of supervision and abandonment. While identification is occasionally clear-cut, e.g., the battered infant, abandoned child or young child with venereal disease, often the physician faces a seemingly vague and ambiguous clinical picture calling for "hard decisions from soft data," a burden shared by all professionals dealing with child abuse and neglect. It is important to emphasize that a physician need not know for certain that maltreatment has occurred in order to initiate intervention in a given family. If there is good reason to suspect that a child is in jeopardy, action is justified ethically and legally. To the extent that clinical skills are refined in history-taking (particularly the assessment of family dysfunction), physical examination, laboratory studies and radiographic interpretation, data can become increasingly "hard" resulting in relatively greater certainty in diagnosis.

### Diagnosis

The Connecticut General Statutes[2] define child abuse as physical injury or injuries inflicted upon a person under the age of 18 by a person given access to such child by such responsible person, other than by accidental means or has injuries which are at variance with the history given of them, or is in a condition which is the result of maltreatment such as, but not limited to, malnutrition, sexual molestation, deprivation of necessities, emotional maltreatment or cruel punishment. A neglected child is defined as one who (a) has been abandoned, (b) is being denied proper care and attention, physically, educationally, emotionally or morally or (c) is being permitted to live under conditions, circumstances or associations injurious to his well-being.

Though some of the above definitions are vague, particularly in the "neglect" category, physicians should develop diagnostic criteria in several categories of child maltreatment. Diagnostic approaches to physical abuse, sexual molestation and failure-to-thrive secondary to nutritional neglect, are particularly essential for practitioners who care for children.

### The Identification of Physical Child Abuse

Excellent reviews of the medical aspects of physical child abuse have been published.[3] [4] Accurate assessment of a child's physical injuries is the essential first step in the overall evaluation of these cases. The "Battered-Child-Syndrome,"[5] the most blatant manifestation of child abuse, refers to the variable complex of old and new fractures, bruises, burns and other less common findings. The more recently described "Whiplash-Shaken Infant Syndrome,"[6] refers to the presence of subdural hematomas and retinal hemorrhages in the absence of scalp or skull injury in an infant. This syndrome is caused by the violent shaking of infants without the infliction of blunt trauma to the head.

Of all injuries inflicted upon children, skin bruises, welts and scars are doubtless the most common. Of greatest concern are bruises in a small infant, bruises

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DAVID L. KERNS, M.D., Associate Director, The National Center for Prevention and Treatment of Child Abuse and Neglect; Assistant Professor of Pediatrics, University of Colorado School of Medicine, Denver, Colorado. Formerly: Associate Director, Waterbury Regional Department of Pediatrics.

of the head and face in any child, and bruises which assume a pattern suggesting abuse with an inanimate object, e.g., belt marks. When assessing a child with bruises, it is important to perform coagulation screening studies to eliminate the possibility of bleeding disorder. In correlating histories given with the bruises present on a child, it is important to estimate the age of the skin lesions present. Wilson[7] has reviewed the "dating" of bruises and the following guidelines may be helpful in determining the age of skin injuries: (1) Initially—red to purple; (2) Within the first week—dark purple; (3) Within the second week—yellow; (4) Complete resolution after 2-4 weeks. When there are visible manifestations in a physical abuse case, it is essential to obtain color photographs of the injured areas for possible later use in court proceedings.

Fractures, particularly multiple fractures in different stages of healing, are a common expression of child abuse. A radiologic bone survey including long bones, skull, ribs and pelvis should be obtained in all cases of suspected abuse. Particularly common are metaphyseal fractures of long bones caused by violent wrenching and twisting of extremities.[8]

Burns account for approximately 10% of injuries in physical abuse.[9] Hot water "dunking" is characterized by burns of the buttocks and perineal area with water levels demarcated on the thighs and the trunk. These burns are often inflicted in relation to toilet-training issues. Cigarette burns, often expressed as circular scars on the palms and soles, indicate a particularly sadistic form of abuse and may indicate psychotic parental behavior.

The most serious injuries, in terms of both morbidity and mortality, are head injuries leading to subdural hematomas. These may be caused by blunt trauma to the skull, with or without skull fracture, or may be secondary to violent shaking of an infant. There is no evidence that "spontaneous subdural hematoma" is actually an entity, and all cases of subdural hematoma should be presumed to be related to trauma. In the "Whiplash-Shaken Infant Syndrome," subdural hematomas are nearly always accompanied by retinal hemorrhages.

### The Identification of Child Sexual Molestation

The sexual abuse of children has been called the "last frontier" of child abuse and neglect. While discovered extra familial assaults, violent or not, are generally reported to law enforcement officials, incest, by far the most common of sexual exploitations of children, may be extraordinarily well concealed for months or years from anyone outside of the nuclear family. In view of the dramatic rise in the appreciation of the incidence of sexual abuse,[10] physicians must consider this diagnosis in a variety of clinical situations. Any person, therefore any child, with venereal disease must be presumed to have had sexual contact of some kind. The mythology of the "contaminated toilet seat" serves only to reinforce the professional's understandable reluctance to deal with this very difficult and sensitive problem. Any child under age 13 with venereal disease must be reported for suspected sexual abuse. Occasionally a young child will simply tell us about his or her sexual activities at home. Kempe[11] has stated that these allegations by preadolescent children should be taken at face value. While adolescents may fabricate or fantasize sexual episodes with family members, younger children rarely will do so. The child with significant emotional or behavior problems may be expressing the psychological upheaval caused by occult sexual mistreatment at home. Too often, chronicles of years of sexual abuse are related by adolescents and young adults, with inestimable developmental and psychiatric damage already having taken its toll.

The evaluation of a child for suspected sexual abuse requires a most patient and gentle approach. History should be obtained, generally in the child's vernacular, of the nature of the sexual activity including exposure, kissing, fondling, hand-genital, oral-genital and genital-genital contact. It is important to learn whether physical violence, committed or threatened, is coupled with the sexual activity. In most instances of father-daughter incest, there is no violent component and passive collusion on the part of the mother is the rule rather than the exception. Physical examination should include careful inspection of the perineal area for any signs of injury including bruises, abrasions, hymeneal and perineal tears and the presence of bleeding, discharges and rectal or vaginal foreign bodies. In addition, attention should be given to the general indicators of physical abuse and neglect. Cultures for gonorrhea from the throat, rectum, urethra and vagina should be obtained and blood should be drawn for VDRL determination. Aspiration and microscopic examination for sperm should be performed. In cases of violent sexual assault, it is crucial that we do not multiply the trauma by "raping" the child in the medical setting with an aggressive, restraining physical assessment. Whatever time is necessary must be spent in properly preparing the child for this evaluation.

### The Identification of Failure to Thrive Secondary to Nutritional Neglect

Nutritional neglect is the most common cause for failure of weight gain in infancy. The malnourished infant will usually fall below the third percentile in weight while maintaining linear and head growth velocities. In very severe cases, weight, length and head circumference will be retarded in that temporal order. These infants will look malnourished with decreased subcutaneous tissue, wasted buttocks, redundant skin and thin extremities. An organic evaluation will fail to reveal underlying abnormalities and when placed on 150-200 calories/kg/day in the hospital, the infants will gain 1-2 ounces of weight per day.

### Clues for the Identification of Child Abuse

While the diagnosis of maltreatment may be readily apparent in some instances, often the physical findings are inconclusive, particularly for distinction of accidental from non-accidental trauma. In such cases, an accurate focus on family functioning will reduce the likelihood of misdiagnosis. The most consistently verified characteristic of abusive parents is that they themselves were maltreated as children.[12] If not physically abused, they were neglected, experienced discontinuity such as multiple foster placements or were sexually molested. Having received these "bad messages" throughout childhood, it is not surprising that they often have very low self-esteem coupled with anger and the feeling that they are unlovable. They are unsuccessful in close, lasting relationships and marital discord, social isolation and the absence of human "lifelines" are often characteristic. Family crises play a significant role in a vulnerable family. The long-standing stress of unemployment, health problems, substance abuse, marital discord, etc., may bring marginal parents to their "wit's end." Acute stress, even spilled milk, generally precipitates the actual abusive incident. Particular attention should be given to the stress of a newly discovered pregnancy or the appearance of a new baby in the household. While the children of psychotic or sociopathic parents are certainly at great risk, it should be remembered that this group constitutes only approximately 10% of all abusive families.[12]

Some children are more vulnerable to be abused than others. Clearly, the happy, cooing, beautiful baby is less likely to be battered than the irritable, relentless, colicky infant. Prematurity, congenital anomalies and chronic illness all place children more greatly at risk. Perhaps the most vulnerable child of all is the one who was unwanted in the first place—an observation that not only is diagnostically relevant but has far-reaching implications in terms of public policy regarding legislation, education and funding of contraception and abortion.

Abusive parents often have unrealistic expectations of their children, both developmentally and behaviorally. The infant who is expected to be toilet-trained by six months of age is indeed in jeopardy. When an infant or child is expected to perform in a way that is developmentally impossible, he is programmed for failure, and verbal and physical retribution are likely to follow leading the continuous erosion of a child's confidence and self-esteem. Parents who have experienced particularly deprived childhoods may turn to their children to meet their never met needs for nurturing and dependency (role reversal). An infant or young child cannot possibly "take care" of a parent in this sense and is again set up to fail, disappoint and provoke the needy parent.

Discrepant histories offered by parents may be helpful diagnostically. If each parent gives a different explanation for a child's injuries, it is quite likely that neither explanation is true. In some instances, histories given are developmentally discrepant, e.g., that a two-week-old rolled off a surface and fell. Delay in seeking medical attention for inflicted injuries is also a common occurrence amongst abusive parents. These families often use multiple health providers in the same community on an episodic basis and "doctor-hopping" and "ER-hopping" are common. Families in distress will often make medical visits that superficially are inappropriate. When an upset parent presents concerns about a child which are quite disproportionate to the reality of the child's condition, dismissal of the case as "just an anxious mother" or as a "turkey" is a serious error. Parents who are mistreating their children or who are afraid that they will do so may reach out for help in very indirect and inadequate ways. When faced with an "over-anxious" parent, the physician should directly and supportively ask the parent if there might not be other important issues at home which are really the cause for distress. Multiple such "inappropriate" visits often precede incidents of serious physical abuse. The astute clinician has the opportunity in these instances to intervene with services before children are injured.

### Confronting Abusive Parents

Few situations in clinical medicine are as uncomfortable for physicians as the communication to parents that there is suspicion that they have abused their child. Abusive parents are generally guilty, defensive and very angry, and in most instances will deny responsibility for a child's injuries. It is crucial that the physician control his own anger in these situations. The understanding that abusive parents are maltreated children who have gotten older can help us to perceive these parents as "hurting" and as victims along with their child. The implicit and explicit message given to the parents should be "I am not against you—I am for you and your child." A common error is the tendency to be too investigative and accusatory. When faced with suspected abuse, the physician has two primary decisions to make in the acute situation: (1) Should the child be hospitalized? and (2) Should a report be made to Protective Services? Many other professionals, including hospital social workers, protective services workers and, possibly, court-related personnel and police will explore the minute details of the case. It is generally not necessary, for example, to know "who did it" in the acute assessment. Unnecessary interrogation at the outset will only serve to further alienate parents and jeopardize a potential helping relationship.

### The Connecticut Child Protection Statutes

The State of Connecticut passed its first child protection law in 1965, and there have since been multiple additions. There are three sections which are particularly relevant to physicians: (1) Any physician who has reasonable cause to suspect or believe that child abuse or neglect (as defined above) has occurred "shall report or cause a report to be made . . . any person . . . who fails to make such a report shall be fined not more than five hundred dollars, (2) Any person, institution or agency which, in good faith, makes the report . . . shall be immune from any liability, civil or criminal . . . which results from such report," and (3) "Any physician . . . shall, after reasonable attempts to advise the parents . . . that he suspects the child has been abused, have the right to keep such child in the custody of the hospital for no longer than 96 hours, with or without consent of the parents . . ."

Reports should be directed to the appropriate regional office of the Connecticut Department of Children and Youth Services (DCYS). An oral report should be made within 24 hours of an incident and a written report should be sent within 72 hours. Contact with DCYS in emergency situations at night or on weekends can be made through the Child Abuse Care-Line (1-800-842-2288).

### Obstacles to Physician Involvement

Helfer[13] has written an excellent review of the obstacles to physician involvement in child abuse and neglect cases. Until only recently has there been significant exposure of medical students and residents to child abuse and neglect. Most physicians in practice have not had training for the management of these very difficult and stressful cases, nor, unless they are psychiatrists, have they had significant training in the kinds of inter-personal skills that are necessary for dealing with these families. The modern management of child abuse and neglect cases is done by multidisciplinary child protection teams wherein the physician must be an egalitarian peer with a number of other human service professionals. This is in contrast to the traditional medical hierarchy which places the physician in a distinctly authoritative position. This political transition may be difficult not only for the physician but for the former "subordinates" as well.

The physician who becomes centrally involved in a child maltreatment case suffers a truly extensive drain of time, finances and emotions for sometimes minimal personal rewards that are hard to identify. Serious consideration should be given to referral of these cases to a subspecialist just as one would with a myriad of other difficult specialized clinical problems. At present in Connecticut there are a number of physicians with particular interest, skill and experience with these cases. Such consultants should also fulfill juvenile court testimonial responsibilities which are uncomfortable and highly impractical for the physician in private practice.

A common concern expressed not only by physicians but by other mandated reporters as well, is embodied in the commonly heard statement "If I report the case, nobody is going to do anything about it, and I'll lose my relationship with the family." While it is true that Protective Services casework loads are very high, that some cases do fall through the cracks and that the child protection system is indeed imperfect, a multitude of services are in fact available to families in Connecticut. The past five years have seen a dramatic expansion of a variety of contemporary approaches to these cases such as multidisciplinary, multiagency dispositional teams, lay therapy (parent aide) programs, Parents Anonymous, special infant day care programs and emergency homemakers. The public sector responses are evolutionary and the approaches of protective services, police and juvenile court are becoming increasingly sophisticated and coordinated with private sector agencies. With all the imperfections in the "system," reporting and intervention are superior to non-intervention which will only ensure chronic maltreatment of children.

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*(This is the first of a series of three articles.)*

# CSMS—AEtna Professional Liability Program

## Semi-Annual Activity Report

FRANCIS P. GINTY

The following is a summary of some of the areas of interest or concern to the Society and the Company at the beginning of the eighth account year.

### I. EXPERIENCE

For purposes of continuity of data analysis, the format of prior reports is retained. The exhibit below reflects loss activity through the end of the seventh Account Year. Six months ago we reported the number of arising claims or suits was *1,075,* an increase of 27.8% over the prior six-month period. At present, there have been *1,207* claims made, an increase of 132 new cases, or *14%* in the last six months. In the short term, it would appear that in terms of claims made, frequency has decreased by approximately 50%. During the same time frames the number of open cases* increased 16.3% in the first six months, and 16.6% in the last six months. The complexity of issues raised in suits brought and the increase of multiple defendants could account for the slight increase of outstanding cases.

Exhibit 1

| *Account Year* | *Incurred Losses*** | *Arising Claims* | *Open Claims* |
|---|---|---|---|
| 1971 | $ 1,261,268 | 111 | 15 |
| 1972 | 2,568,478 | 207 | 46 |
| 1973 | 2,248,501 | 220 | 75 |
| 1974 | 2,891,200 | 262 | 97 |
| 1975 | 4,201,575 | 237 | 122 |
| 1976 | 1,388,947 | 129 | 50 |
| 1977 | 597,068 | 41 | 29 |
| TOTAL | $15,157,037 | 1,207 | 434 |

*"Open cases" are still in the process of settlement, litigation, and/or other disposition.

The *unloaded*** loss experience increased by $4,241,815 or 25.7% in the last six months. The prior six months increase represented a 12.2% increase. In the periods reported on in the last 18 months, the average cost per claim has increased from $8,993 to $10,154 to $12,550 at the present time. While there had been a relatively consistent increase of severity in each account year of $1,100, the present period average cost per claim ($2,404) has more than doubled in six months. This data tends to confirm the trend projections reflected in the Annual Report for the 1977/1978 Account Year. Severity is at present increasing at a rate somewhat greater than anticipated, as reflected in the new 1978 rates.

Earlier observations reflected in these reports predicted attorneys cannot (in the long term) afford the attendant expense of preparation of cases without questions of fact as to liability. Injury exposure, however, reflected in fewer cases, but larger in the selections made, clearly accounts for the higher average cost of cases disposed of.

### II. INCIDENT REPORTING

The practice of tracking incidents reported in past account years was intended to monitor the specialties of medicine most vulnerable to actual claim activity. This information was meaningful in the determination of approaches taken in the loss control and education aspects of the program. As the data base grew, the exhibit below (which reflects only actual claims made) replaced the usual appendix of reported incidents by specialty. Over the years, the same high risk specialties produced, not only larger numbers of incidents reported, but actual claims made and dollars reserved by AEtna's Claim Department. The October

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MR. FRANCIS P. GINTY, AEtna Administrator for the CSMS Professional Liability Program, now in its sixth year of existence. *This report was issued to the CSMS Committee on Professional Liability in November, 1978.*

**Unloaded loss includes both closed, paid claims, and reported open claims for which reserves have been set aside at currently estimated value. It does *not* include actuarial loading factors for claims incurred but not yet reported (IBNR), future loss development and inflation, or future loss adjustment expense (legal fees and costs).

results suggest no change, except perhaps for moderation in frequency of claims.

The past practice of tracking geographic locations by towns and by incidents reported as an exhibit has been discontinued. The tracking by the Account Supervisor continues to demonstrate, however, a correlation between the physician/population ratio in the Western and Eastern portions of the State, and the lawyer/patient ratio in the central portions. Clearly, the Metropolitan areas of the state continue to produce a higher incidence of claim activity correlated with the number of physicians, hospital beds, practicing lawyers and population. This is consistent with data reported nationally by studies of the malpractice problem. While this impacts the frequency of claim activity, there is no data to suggest severity is moderating

## III. CLAIM CLIMATE

A careful review of the lawsuits being brought against Society members suggests they stress the extent of injury, rather than the allegations of actionable negligence on the part of the physicians. These represent the facts and not the issues focused on in recent trials.

In May of 1977, 345 lawsuits were pending against program doctors. In the next year they increased to 395. In the last six months, they have decreased to *383*, pending as of October 1, 1978. While claims made against physicians increased by 14% in the last six months, the number of law suits brought decreased from 50 in the prior period, to 38 new suits in the last six months.

A careful review of arising losses confirms a prediction made in earlier reports. Fewer incidents of malpractice are being reported, but suits brought reflect greater injury exposure. Fewer attorneys are involved than heretofore, and selection of cases is based on high injury exposure. The suits are being brought by an elite core of practiced plaintiff's counsel who are experienced in medicine, skilled in trial technique and motivated by settlements or awards anticipated from high injury exposure, with a fair chance of recovery. Thus, the predicted thrusts of litigation, due to the high cost of preparation of a case for trial and the skills needed for successful prosecution appear to be the present criteria in the selection of cases. Professionals, few in numbers and reluctant to take but the best of referred cases, have replaced the amateurs who plagued us with the numbers, but lesser or no damage exposure in past years.

## IV. CLAIM DEFENSE PANELS

As an extension of the joint Loss Control and Education program, the panels represent the "case study" approach to education and prevention of losses. In the first six months of the seventh Account Year, 21 new cases were reviewed. Since the last report to the Society *30* cases have been reviewed, reflecting the increased number of cases involving multiple defendants. As of October 1, *246* or roughly 25% of all claims or suits arising in the program since 1971 have had a formal and in-depth review, involving in excess of 600 member physicians as regular or guest panelists.

Very early on, the Account Supervisor observed that national data from reliable sources such as the National HEW Commission's report to the President and subsequent reports by the National Association of Insurance Commissioners, confirmed that approximately half of the actions brought in malpractice against the physicians had some merit on the facts. Prior activity of the Panels supported that assumption, as represented by the votes taken. The table below reflects the Panels have found, as of the present, a 49.6% degree of culpability in cases reviewed—an increase of 2.1%.

With a statistically large present sample of cases, Counsel to the defendants and AEtna's Claim Department had accepted the response of physician peer review as a reliable evaluation of exposure (from the medical facts) and have responded appropriately. Six months ago, 46% of cases reviewed had been disposed of. As of the present, 50% are pending disposition.

Exhibit II

| | | |
|---|---|---|
| *Cases Reviewed* | *246* | |
| *Vote* | | |
| Malpractice | | 37 |
| Compromise (no malpractice; difficult to defend) | | 85 |
| Defend (no malpractice; defensible) | | 124 |
| *Disposition By Vote* | | |
| Settle | | 49.6% |
| Defend | | 50.4% |
| | | 100.0% |
| *Percentage and Method of Disposition* | | |
| 1. Disposed | 50% | |
| a. Settled | | 66.6% |
| b. Tried | | 9.8% |
| c. Withdrawn or Dismissed | | 23.6% |
| 2. Pending | 50% | |
| | | 100.0% |

## V. LOSS CONTROL AND EDUCATION

Improvements in the quality of care ultimately *may* diminish the number and severity of medical injuries to an irreducible minimum. Claims and law suits based on those injuries will not reach that minimum, however, unless and until the non-technical aspects of patient/physician and patient/hospital relationships reach optimum refinement. These are represented by the behavioral changes on the part of physicians and attitudinal change by the consumers of health care.

AEtna's Loss Control and Education program has emphasized, aside from medical judgment, matters which have been observed to aggrevate patients, enhance their willingness to litigate, and impair chances for successful defense. Recognizing the non-technical aspects of the prudent practice of medicine present an area for prevention of malpractice litigation, we have chosen to concentrate much of our efforts on these factors. As an insurance carrier, we can neither impose improvements upon the technical aspects of medical practice, nor impose sanctions for deviation from accepted standards of practice. Our efforts, reflected by the programs presented to the physicians, stress changes in human behavior which impacts on the physician/patient relationship, in an effort to deter claims. There are, however, limitations on the extent to which serious, avoidable incidents can be legitimately controlled after the fact.

## VI. LEGISLATIVE ACTIVITY

Early opinion of others express the belief that legislation was the answer to the malpractice problem. The Professional Liability Committee of CSMS recognized this was not a fact. Nevertheless, they advanced the enactment of certain legislation, devised to provide physicians with at least equal footing with prejudicial existing legislation. The Society can look back with some pride that none of the legislation enacted has thus far been subjected to the test of constitutionality and struck down.

The Society and counsel, having examined the remedy of legislation, and accepted the proposition that unencumbered access to jury trials would be weighed heavily by courts asked to review legislative measures taken in their behalf to alleviate the problem. Further, while the courts uphold the legislature's freedom to alter the traditional court system where the alternatives are necessary to deal with the malpractice problem, it does not follow that the rights of all parties to litigation have been protected.

Before the 1979 session, the Society in cooperation with CHA and AEtna's Law Department will make decisions on a legislative package. Installment Payments, as an equitable distribution of judgements owed to injured patients, and the admissibility of collateral sources of income to off-set expenses due to injury, remain important issues. Attacks in recent trials on the Peer Review statute providing confidentiality and immunity for physicians participating in Review Panels suggest review of that legislation may be indicated. Counsel to the Society, CHA and the AEtna, depending on recent developments, may suggest yet more legislation for the coming session of the General Assembly.

## VII. CONCLUSION

Aside from the considerations raised or implied in the narrative and data in this report, the prime issue remains accountability for patient injury. It is a fair assumption that Connecticut physicians have recognized and reacted positively to a demand for accepted attention to and management of professional competence, and the accountability. The criteria for these can be cited by either side in the debate over whether an injury was caused by substandard performance. The malpractice "crisis," misunderstood and characterized as a "crank" reaction by a consumer-oriented patient population, is now viewed by responsible physicians as a reality. It has been demonstrated by high awards to patients, approved by physician's peers, upheld by the courts, and paid by responsible insurors.

Malpractice was the last area to grow out of the negligence field because it was thought to be so complex and difficult. Ten years ago, the consumer accepted a bad medical result and bought medicine's explanation of fate, or an ideosyncratic reaction. Not so today. The public is more sophisticated for reasons other than the newly developed skills of lawyers with the ability to take a complex set of facts and to present them in a way a jury can understand. The dictum of the law which states only expert opinion can decide the issues, and traditionally accepted by physicians as a fact, is under attack. Recent verdicts in Connecticut suggest jurors have rejected the law, and evaluated the facts with independent judgment.

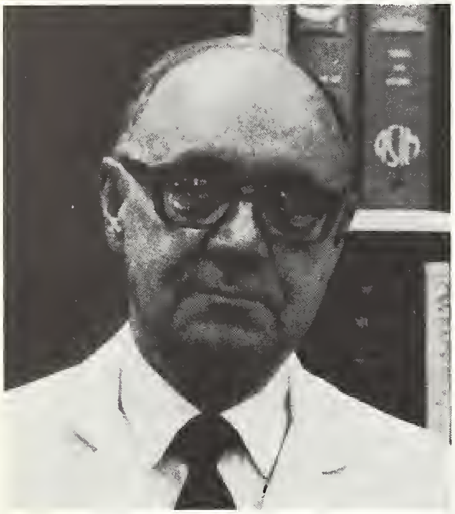
Having defined the problem, and recognized and accepted the consequences, can we find alternatives to change the result? Physicians have and may still claim that this inquiry is beyond the competence of a jury, and must be left to specialists in the professional community. Many non-professionals, along with professionals in other fields, are quite unimpressed. The conflict of opinion frustrates the public at large.

In the expanding universe of suits alleging professional malpractice, there develops a need for some source of accepted attention to and management of professional competence; that is, for the aforementioned accountability. This presents a challenge.

A review of the literature which examines the role of professional associations or societies suggests they undertake a more responsible role in the task of standard setting and monitoring of compliance. Otherwise, it is suggested, such burdens will be imposed by government fiat. There does not exist for the moment any suggestion that Connecticut medicine needs or desires regulation beyond that which is within the province of the individual practitioner. "The buck stops here"—at least for the present.

# “THE PHYSICIAN IS A DECISION MAKER, AND ALMOST EVERY DECISION HE MAKES COSTS OR SAVES MONEY.”

*—Dr. William Felts, Past President,*
*American Society of Internal Medicine*



More and more physicians today are beginning to realize the extent of the economic influence they have, and are finding ways of holding costs down.

A number of studies show that the more physicians *know* about costs, the more they try to *reduce* them.* And this reduction can be done without reducing the quality of care to the patient.

How are they doing this? As a start they have become thoroughly familiar with the costs they incur on behalf of their patients. They know how much an X-ray costs, how much their hospital charges for routine lab tests. They’re requesting copies of patients’ hospital bills. And asking their hospitals to print the charges for diagnostic tests right on the order sheet.

What else are physicians doing? Minimizing their patients’ hospital stays, whenever possible. Reevaluating routine admissions procedures. Questioning the real need of the diagnostic tests they order for their patients. Avoiding duplicate testing. Trying to discourage their patients’ demands for unnecessary medication, treatment or hospitalization. Compiling daily logs of their medical decisions and what they cost. And more.

More physicians today realize what a tough problem we’re all faced with. They know this is a challenge for medicine. And that physicians are in the best position to deal with and solve the problem.

**PATIENT CARE Magazine—Outlook 1977. “Face-Off: Cost Containment vs. Chaos,” January 1, 1977.*

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# Report on Litigation to the AMA House of Delegates

NEWTON N. MINOW, ESQ.

I am honored to be here today at the invitation of Dr. Hunter and Dr. Rial and to report to you on the status of the litigation in which the American Medical Association is a party. I will describe briefly the legal actions in which the Association is involved and explain the reasoning behind the positions that the Association is taking in each case.

Our firm, Sidley & Austin, was first retained by the AMA in 1974. Since that time, we have been carrying out the Association's determined effort to maintain individual freedom and independence in the practice of medicine as a learned and noble profession. The first case in which we represented the Association, for example, raised the question of whether the Department of Health, Education and Welfare could lawfully promulgate regulations which unduly interfered with the exercise of physicians' professional judgments regarding the hospitalization of patients. As many of you will recall, we succeeded in having those regulations struck down by a federal district court which was affirmed by a Court of Appeals. You will be interested to know that in June of this year, the government published an announcement in the Federal Register finally conceding that these regulations were unlawful.

We live in a time of increasing governmental intervention in the delivery of medical care. Your Association has, therefore, increasingly taken to the courts to limit bureaucratic interference with the practice of medicine and governmental disregard for the rights of patients and the physicians who serve them. The AMA's efforts in this area have continued during the past year.

Last spring, the Secretary of Health, Education and Welfare announced his intention to publish a list of all physicians who treated Medicare beneficiaries in 1977 and to attribute to each physician the amount of income that he or she allegedly had received in Medicare payments. The only justification that the Secretary has offered for this invasion of privacy is that publication of this information might stimulate debate on the costs of health care. Representatives of this Association pointed out to Secretary Califano that this goal could be achieved equally well—but without interfering with anyone's privacy—by not identifying individual physicians or simply by breaking down expenditures by medical procedure rather than by provider. Yet the Secretary refused to compromise.

Consequently, your Association took the matter last June to federal court in Chicago. We were successful in obtaining a court order preventing the proposed publication of the information. At the suggestion of the Judge, we then intervened in a pre-existing case in Jacksonville, Florida in which another court had granted a similar request in a suit previously filed by the Florida Medical Association. This fall the United States District Court in Jacksonville issued a writ of injunction restraining publication of any of the information on the proposed list. Despite the determined efforts of the government to have this injunction lifted, I can report to you that HEW is still enjoined from publishing the list. A battle on this issue lies ahead, and I assure you that we will continue to make every effort to see that it is never published.

At just about the same time that HEW indicated that it would publish the list of the Medicare-related incomes of identified physicians, the Federal Trade Commission promulgated a Trade Regulation Rule entitled "Advertising of Ophthalmic Goods and Services." Among other things, this Rule would invalidate all state laws governing the advertising and

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NEWTON N. MINOW, ESQ. Managing partner in the law firm of Sidley & Austin, Chicago, Illinois. Formerly Chairman, Federal Communications Commission; Member of Board of Trustees, Mayo Foundation. Report delivered at the Interim Meeting of the AMA House of Delegates, December 3, 1978.

dispensing of ophthalmic goods and services which the Commission deems unfair. The Rule has direct and immediate ramifications for ophthalmologists. Of great significance, the Rule would, if upheld by the courts, establish the astonishing authority of the Federal Trade Commission to override the laws and policy decisions of state legislatures in medical matters whenever the Commission considers these decisions unfair. It could serve as a precedent which might lead the Commission to try to strike down other state laws such as those regulating medical licensure, medical discipline, and medical practice. Thus, the Ophthalmic Goods Rule poses a threat to the practice of medicine which far transcends its immediate terms.

Your Association has therefore challenged the Federal Trade Commission by turning to the courts. Along with nine sovereign states and the American Optometric Association, we sought review of the Ophthalmic Goods Rule in the United States Court of Appeals in Washington. Our brief was filed in October, and the states filed theirs in November. The brief of the Commission is due this month. If the Court adheres to its customary time schedule, the case will be heard in late spring, and a decision will follow sometime late 1979 or 1980. I think it likely that this case will ultimately reach the Supreme Court.

Your Association is also resisting efforts by the Federal Trade Commission to remove it from the process of accreditation of medical schools. In an unprecedented move, the Commission appeared before the United States Office of Education last year to urge that the Liaison Commission on Medical Education not be recertified as the official accrediting agency for medical education. It argued that because some of the members of the LCME were appointed by the AMA, the LCME could not be counted upon to make impartial decisions on matters of accreditation. The notion that a professional association should not be involved in such matters is of course reprehensible. The AMA was founded to improve the quality of medical education and has worked continuously for over a century to effectuate this goal. Accordingly, both your Association and the LCME strongly opposed the position that the FTC took before the Office of Education. After a hearing and a review of past performance, the LCME was provisionally recertified for two years as the officially recognized accrediting agency for medical schools. That battle will again be fought next year.

Undaunted, the Federal Trade Commission launched its own investigation of alleged efforts by the AMA to restrict the number of physicians graduating from medical school. That investigation has now been pending for over a year. A formal complaint has not as yet been issued. Interestingly, the Commission's staff person with primary responsibility for health matters recently was quoted in the press as saying that the AMA may not have restricted entry into medical schools after all. The facts may be getting through.

In another area, the facts have not been getting through. I turn now to the attack brought by the Federal Trade Commission on the Association's ethical standards. In 1975, the FTC issued, without any prior notice or investigation, a complaint challenging the ethical principles applicable to advertising and solicitation by physicians. The FTC also attacked the ethical guidelines applicable to a variety of contractual arrangements entered into by physicians—for example, the ethics of a partnership between a physician and a lay person.

When this proceeding was instituted in December of 1975, we attempted to settle the case. We hoped to settle for two reasons. First, we knew that it would be difficult to find a less favorable forum for resolution of the issues raised by the case than the Federal Trade Commission. We feared that we would not get a fair, unbiased proceeding because the Commission had already displayed its hostility to organized medicine. Furthermore, the administrative law judge assigned to the case had been for many years a prosecutor for the Commission. Finally, we knew that, incredible as it might seem to a non-lawyer, we would have to appeal the initial decision of the administrative law judge to the full Federal Trade Commission—the very people who directed the complaint in the first instance.

Indeed, just last month, all four members of a panel reporting to the National Commission for the Review of Antitrust Laws and Procedures recommended that the FTC's antitrust litigation responsibilities be terminated or significantly modified. As panel member Professor Glen Weston of George Washington Law School observed, the majority of Administrative Law Judges have served as FTC prosecuting lawyers. Moreover, there is also the problem that three of the five commissioners had no significant training in antitrust law before their appointments.

Our second reason for seeking to settle was that since the case would involve the production of thousands of documents and scores of witnesses from around the country, we knew that it would be exceedingly costly. The investigation of each document and the preparation of each witness is a difficult, time-consuming, and costly task. So we hoped to be able to save the Association the enormous expense that the case would inevitably entail.

But the staff of the Commission flatly rejected our position that professional associations, including the AMA, have not only the right but the responsibility and duty to see that advertising by their members is limited to truthful, objective, verifiable information that will help enable patients to make an informed choice among physicians. Instead, the Commission insisted that the AMA and state and local medical societies should play absolutely *no role* in setting standards of ethical promotional practices by their members. The staff insisted that advertising by physicians should be regulated exclusively by the government. This was a position that neither you nor we could accept. For it is premised on the proposition that professional men and women cannot be trusted to regulate themselves in the public interest. And that proposition is fundamentally inconsistent with the Association's basic principles.

The decision of the Administrative Law Judge was announced this week. After reading it, I submit that George Orwell's 1984 has arrived six years early. The world of Big Brother, seeking to take over the independent, professional practice of medicine, has arrived in 1978.

I wish there were time to undertake an extensive legal analysis of the decision. I will limit this to a summary of our arguments and the manner in which they were resolved.

First, the FTC has jurisdiction only over persons, partnerships, and for-profit corporations. Since the AMA is clearly not a person or a partnership, the question is whether it is organized for the profit of itself or its members. We demonstrated that the vast majority of the Association's activity is devoted to scientific, educational, and public health matters. The Judge, however, chose to discount this evidence and to find that the AMA is organized for the profit of its members because it has done such things as offer its members a retirement plan and oppose enactment of certain forms of national health insurance.

Second, we argued that the AMA should be judged on its current ethical positions, not on the basis of statements from the 1930s, 40s, 50s and 60s made in a vastly different legal and social climate. The Judge absolutely refused to accept this argument and virtually ignored the 1977 edition of the *Opinions and Reports of the Judicial Council.*

We pointed out that questions of ethics are local matters which arise locally and are resolved locally. We demonstrated that state and local medical societies are autonomous organizations which make decisions independently of the AMA. Apparently ignoring this evidence, the Judge found that there is a grand conspiracy among the AMA and state and local medical societies to stifle all advertising and subvert any innovative form of health care delivery.

I could go on and on and on, but the Opinion is 312 pages, single-spaced. The one positive note is that this Order is not a final one. It still must go before the full Federal Trade Commission, the United States Court of Appeals, and possibly the Supreme Court before it becomes final. While we are not optimistic about the results before the FTC, we are hopeful that we shall find justice when we have our day in the federal courts. We will not rest until this misguided decision—so contrary to the public interest and so alien to our basic American traditions of freedom—is overturned.

I say that because I believe that the Initial Decision of the Administrative Law Judge is a direct assault on the entire concept of professionalism and will, if allowed to stand, lead to the deception and injury of thousands upon thousands of innocent patients.

The Order entered by the Administrative Law Judge would forbid the AMA and its constituent and component medical societies from involving themselves in any way in the advertising, promotional practices, or contractual arrangements of physicians. Thus, if an AMA member were to make misleading claims about his or her skill or fees, the medical societies would be powerless even to advise the physician of the problem or to declare the advertising unethical. All that they could do would be to complain to Big Brother—in the form of the FTC.

It must be asked: How could this Administrative Law Judge have reached these results? The short answer is that he distorted or ignored much of the evidence and most of the applicable law.

In our defense of the case, we offered witnesses who had literally been mutilated after responding to misleading advertisements and high pressure tactics of certain advertising physicians. We have testimony from the mother of a woman who died as a result of an abdominoplasty performed by an advertising physician after several other physicians had advised the patient that she was unacceptable risk for surgery. On the witness stand, these patients begged medical societies to do something to prevent the fraud and incompetence to which they had fallen victim. Now a Federal Trade Commission employee has said that the medical profession is prohibited by law from doing anything to regulate this kind of behavior. And it is equally forbidden to take any action against those within its ranks who advertise the worst sort of abortion mills, who claim that they will guarantee a weight loss of 20 pounds within two weeks, and who make other statements which lead patients to choose physicians on the basis of who is the best advertiser rather than who is the best physician.

As outrageous as this is, there is another aspect of the Administrative Law Judge's Order which is even more sweeping. And that is this: The AMA may not even establish ethical guidelines governing the advertising and solicitation practices of its members unless it first obtains "the permission and approval of the Federal Trade Commission". This provision has staggering implications for the First Amendment, the traditions of professionalism, and ethical standards which have always been basic values in our society. This provision would mean that federal officials in

Washington, and not the profession itself, would determine what constitutes ethical behavior by physicians.

I am reminded of the poem "The Second Coming" by William Butler Yeats. In that poem, Yeats said, "The best lack all conviction/While the worst are full of passionate intensity". In its misguided zeal, the Federal Trade Commission has been full of passionate intensity. But we as professionals must never lose the courage of our convictions. We will do everything we can to seek reversal of this attempt to put the independent practice of medicine in the hands of government.

In the cases discussed thus far, our adversary has been an agency of the federal government. I turn now to another set of cases in which the Association is involved. Here, our opponent is not the government but a number of individual chiropractors. These chiropractors have brought actions against the AMA and several other defendants in three different forums—federal court in Philadelphia, state court in New Jersey, and federal court in Chicago.

All three of these actions have several features in common. Each is brought under antitrust laws which declare it unlawful for two or more persons to combine or conspire to restrain competition. Plaintiffs in each case contend that by declaring it unethical to associate professionally with unscientific practitioners, physicians have combined to prevent chiropractors from competing within the limits of their licenses. More specifically, plaintiffs in each case take the position that physicians have conspired to restrain competition by uniformly denying chiropractors access to the use of diagnostic procedures that they require in order to practice within the scope of their license.

At the same time, the three actions differ from one another in some respects. The Pennsylvania and New Jersey cases are each brought by local chiropractors concerned with local conditions. The Chicago case, by contrast, is brought by chiropractors from different parts of the United States. They appear to be concerned primarily with the effect of various medical society positions on chiropractic as a whole. Thus, the relief they seek is infinitely more sweeping than that sought by plaintiffs in Pennsylvania and New Jersey. They have asked, for example, for millions of dollars in damages and for one million dollars for each of the next ten years to establish and operate a research institute for the advancement of chiropractic.

Finally, the three cases have this in common: The defense of each lawsuit has required a heavy financial outlay by this Association, which because of its size and public visibility is inevitably viewed as the principal defendant. The expenditure of resources that has occurred until now will be dwarfed by the expenses that will be incurred if the cases go to trial. Moreover, any adverse decision against the AMA in a litigated case will in all likelihood provoke treble damages lawsuits against the Association and against state and local medical societies by chiropractors throughout the country.

In view of the costs and risks of these lawsuits, we believe that the most responsible course is to explore settlement on reasonable terms—just as we would explore settlement of any case of this nature. In fact, as you know, a tentative settlement agreement has been reached by the Association in the Philadelphia case. Under the terms of this tentative settlement, the AMA acknowledges simply that each individual physician must decide for him or herself whether and in what circumstances to accept referrals from a chiropractor. It acknowledges that chiropractors are licensed limited practitioners as that term is used in the *Opinions and Reports of the Judicial Council.*

The Association is represented by a different local law firm in each of these chiropractic cases. Our firm has acted in an overview advisory capacity to the AMA in these suits. We have carefully reviewed the tentative settlement in light of the applicable law. On the basis of this review, we conclude that this settlement is a reasonable one and is in the best interests of the Association. Our opinion on this matter is shared by the able Philadelphia law firm which represents the Association in this case on a day-to-day basis.

Four specialty societies and some individual physicians, however, disagree with our assessment. Representatives of these societies feel so strongly about this subject that they have taken legal steps to try to prevent finalization of the settlement. While we respect their views, our own independent judgment differs from their opinion.

As we understand it, the position of these specialty societies is based on three concerns. First, the societies believe that an acknowledgement that chiropractors are licensed limited practitioners would give chiropractic legitimacy as a healing art. Second, they fear that settlement of the Philadelphia case would have an adverse effect on the defense of the Chicago case. Third, they contend that the tentative settlement would violate Principle 3 of the Principles of Medical Ethics, which provides that a physician shall not "associate professionally" with anyone who practices a method of healing not founded on a scientific basis. These are very important and deeply felt concerns, all of which deserve respect—and answers.

First, in acknowledging that chiropractors are licensed limited practitioners, the settlement merely recognizes the fact that chiropractors have been licensed under the law of every state to perform certain limited procedures prescribed by state law. Much as we might wish it otherwise, the state legislatures in all fifty states have already considered chiropractors as licensed limited practitioners. The tentative settlement in no way changes the legal status of chiropractors.

Moreover, it is basic to understand that the settlement terms agreed upon by the AMA in no way obligate any physician to have any contact whatsoever with any chiropractor. If an individual physician considers chiropractors to be unscientific cultists, as far as the AMA is concerned that physician need never accept a referral from a chiropractor. Indeed, anyone who sought to force a physician to treat patients sent by a chiropractor, be it the government, a hospital board, or a group of individuals, would be acting contrary to the AMA position.

Second, both in our judgment and that of the lawyers representing the Association in Philadelphia and in Chicago, the settlement does not jeopardize the defense of the Chicago case. It does not in any way constitute an admission that the AMA has violated the law. In fact, it makes no statement about legal liability. What it does do is make clear that the AMA's position is that it is up to the individual physician to decide whether or in what circumstances to accept patients sent by chiropractors. If anything, therefore, the settlement helps our defense in Chicago because this position is far easier to defend under the antitrust laws than is a blanket prohibition on accepting referrals in any circumstances. Moreover, the tentative settlement removes the possibility of an adverse ruling in the Philadelphia case. In this connection, we are of the opinion that your Board of Trustees has appropriate authority to settle lawsuits when it believes that settlement is in the best interest of the Association.

Third, the settlement is, in our judgment, consistent with the prohibition in the Principles of Medical Ethics against associating professionally with an unscientific practitioner. The Judicial Council's interpretation of this prohibition declares it unethical for a physician to enter a course of treatment jointly with an unscientific practitioner. It does not interpret the Principles to forbid accepting a referral from such an individual and thereafter dealing with the patient exclusively. As I read the Principles as interpreted by the Judicial Council, the tentative settlement is in complete accord with the Association's policy that a physician may accept a referral from an unscientific practitioner as long as the physician doesn't undertake a course of treatment together with such practitioner.

Under ordinary circumstances, a speaker's platform is not the best place for a lawyer to give advice to a client. But the circumstances facing the AMA today are not ordinary. I will therefore briefly discuss some of the antitrust implications of the chiropractic litigation.

Although the Sherman Antitrust Act was enacted in 1890, it was not until *Goldfarb* v. *Virginia State Bar Association, et al.* was decided in 1975 that the Supreme Court first declared that there was no "learned profession" exclusion from application of the Act. As a result, physicians, lawyers—all professionals—are now subject to the Sherman Act. Under this Act and analagous state statutes, a concerted refusal to have anything to do with certain providers of goods or services, under threat of disciplinary action, is a violation of law.

Neither this House nor the Judicial Council has ever stated that a physician may not individually decide to accept as his or her patient a person sent for treatment or diagnosis by a chiropractor. As a matter of fact, if the AMA or any other medical organization threatened to discipline for unethical conduct members who accept patients referred by chiropractors, regardless of circumstance, that organization would be in direct violation of the Sherman Antitrust Act.

Chiropractic as a system of treating *all* disease by spinal manipulation or adjustment was described by the AMA House of Delegates in 1966 as an "unscientific cult" and a "hazard to rational health care." The AMA is clearly within its "first amendment" rights when it continues to express its concern about the danger of unscientific methods of treatment. But it should not take a position which would make it unethical for a member to decide individually to accept as a patient a person referred by a chiropractor.

As you know, Section 4 of the Principles of Medical Ethics requires physicians to "observe all laws." Judicial Council Opinion 3.70 is consistent with the law and reflects the long-standing position of the AMA both prior to the *Goldfarb* decision in 1975 and since. We are unaware of a single instance in which a surgeon has been disciplined by the AMA or any medical society for performing surgery on a patient referred by a chiropractor. Nor are we aware of any radiologist or other physician who has been censored or admonished for accepting for treatment or diagnostic services a patient sent by a chiropractor. This Association should not now adopt a position contrary to law and contrary to its own ethics which require that physicians observe the law.

You are committed to improving people's health through scientific medicine. I share your outrage when innocent patients are exposed to unscientific practices contrary to their best interests. You who are devoted to the welfare of the patient must be appalled when state legislatures permit a system of treatment which runs directly contrary to this goal. But your concern for the patient and for quality care cannot lead you into positions that violate the law—in this case, the antitrust laws—no matter how well-intentioned those positions are.

In June of 1977, the Chairman of the Federal Trade Commission said: "The Federal Trade Commission is not a health or medical agency. To paraphrase a President who was hardly our patron saint, Calvin Coolidge, 'The business of the FTC is business.' And we recognize, along with most Americans, that the delivery of health care is business, an industry of vast proportions and vital effect. Health Care has become our business. I have no apologies for that; in fact, one might ask: 'What took the FTC this long?' "

As men and women trained in a noble and learned profession, you are now on notice that parts of our government claim that the medical profession is not a profession but a business—and that health care is now the FTC's business. At a time when the President and many members of Congress are saying that our country is over-regulated, the FTC wants to regulate the practice of medicine. I read you one ominous sentence from the decision of the FTC Administrative Law Judge: *"Respondents will be permitted to participate in setting ethical guidelines for the conduct of their members after first obtaining permission and approval of the Federal Trade Commission."*

1984 has arrived in 1978. You, the members of an ancient and honored profession, are not even to participate in setting your own ethical standards without first getting the permission and approval of the federal government. I don't have to tell you how much is at stake here, fundamental principles far beyond this particular case.

I serve in another cause with Dallin H. Oaks, President of Brigham Young University, who is also a leader of the American Association of Independent Colleges and Universities. President Oaks said a few months ago: "I contend that government authorities need to be just as careful about regulating schools, colleges, and universities as they are about interferences with newspapers, public meetings or any other delivery mechanism for the products of free speech. As the essential transmitters of our culture and as the source, teacher, and practitioner of values in our society, schools, colleges and universities must be assured a wide range of freedom for their activities of discovery, advocacy, and practice."

The same observation is true with respect to the practice of medicine. The freedom to practice medicine is at stake, not only for yourselves, but for your patients and for future physicians and future patients. It is essential that all of you remain united to preserve your freedom—and the freedom of your patients. I am proud to carry on the battle to maintain professionalism, for it is a just one.

In accepting the Nobel Prize for literature, William Faulkner declared, "I believe that man will not merely endure: He will prevail." In acting as counsel to this great Association, I share Faulkner's faith. I believe that as long as it stands together, the medical profession will not merely endure. It will prevail.

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## Few Patients Seek Second Opinions

As HEW mounts yet another campaign to get patients to seek second opinions on surgery, it is becoming apparent that so far the new benefit program is not a booming success. Out of 20,000 Blue Cross-Blue Shield subscribers in Illinois who underwent surgery recently, only 14 asked for second opinions before their operations, even though it would have cost them nothing. In New Hampshire and Vermont, out of 4,000 persons who had surgery during a 1-month trial of the new benefit, only 1 asked to be examined by a second specialist.—*Modern Medicine,* Dec. 15, 1978– Jan. 15, 1979.

# AMA Involvement in Litigation

For the information of the House of Delegates, the Board of Trustees is submitting the following summary of AMA involvement in litigation for the past three years:

**I. Litigation Instigated by Office of General Counsel**

*AMA* v. *Weinberger*—On February 20, 1975, for the first time in AMA history, suit was filed against the Secretary of Health, Education and Welfare challenging the validity of and the Secretary's statutory authority to issue regulations mandating utilization review of the medical necessity of Medicare hospital admissions within 24 hours. For a year the AMA had opposed attempts by HEW to require preadmission review of Medicare admissions and had met with the Secretary to object to the Secretary's efforts to exceed his statutory authority by interfering in the professional judgments of physicians as to the need for hospitalization of their Medicare patients.

On June 5, 1975, Judge Julius Hoffman of the Federal District Court in Chicago issued a preliminary injunction finding that the Secretary had exceeded his statutory authority and acted in violation of Section 1801 of the Social Security Act that provides, in part: "Nothing in this title shall be construed to authorize any Federal Officer or employee to exercise any supervision or control over the practice of medicine or in the manner in which medical services are provided. . . . " The government appealed and the preliminary injunction was upheld by the Federal Court of Appeals for the Seventh Circuit. The Secretary then withdrew the utilization review regulations.

*AMA* v. *Secretary of HEW*—The AMA filed suit on July 25, 1975 in the Federal District Court in Chicago challenging the validity and constitutionality of regulations to establish a maximum allowable cost for multiple source prescription drugs under the Medicare and Medicaid programs. The AMA contended that by establishing a maximum allowable cost for multiple source prescription drugs, hospitals would force physicians to prescribe the generic drug available at the MAC price even if, in the physician's judgment, a brand name product would be the drug of choice for the patient. On March 7, 1977, the Court upheld the validity of the regulations basically on the grounds that the government has the right to regulate that which it subsidizes. The regulations primarily established reimbursement levels and did not interfere with physicians' judgment, in the opinion of the Court, since a physician could certify on the prescription that a particular drug was medically necessary and assure full reimbursement. The Court further relied on what it perceived to be a congressional intent to assure cost-lowering reimbursement methods in the Medicare and Medicaid programs.

Even though the case was not won, filing it had a beneficial impact. The Secretary has moved slowly and cautiously in implementing the regulations knowing that any action on his part that is not solidly based in law and fact is subject to challenge.

*State of North Carolina, AMA, et al.* v. *Joseph A. Califano*—On April 27, 1976 the State of North Carolina at the urging and with the assistance of the AMA filed suit against the Secretary of HEW to contest the constitutionality of the National Health Planning and Resources Development Act of 1974 (PL 93-641) in a Federal District Court in the Eastern District of North Carolina. The AMA, North Carolina State Medical Society and State of Nebraska intervened as plaintiffs in the action. The suit basically challenged the constitutionality of the Act insofar as Congress had delegated to the Secretary the right to determine for states what aspects of the health care field should be regulated even if such legislation, such as certificate of need, had been found unconstitutional by the highest court of a state. In the case of North Carolina, the North Carolina Supreme Court prior to enactment of PL 93-641 found a certificate of need law violated the state's constitution. A three-judge Federal District Court upheld the constitutionality of the Act on November 9, 1977. Appeal was filed in the United States Supreme Court which affirmed the lower court decision without opinion in April 1978.

*AMA* v. *FTC*—On June 2, 1978, the AMA filed a petition seeking review of the Trade Regulation Rule of the Federal Trade Commission on the advertising of ophthalmic goods and services in the Federal Court of Appeals for the District of Columbia. Eleven state governments are now co-plaintiffs in the action. Oral argument will not be scheduled before June 1979. The suit challenges the authority of a federal agency to issue a Trade Regulation Rule that supersedes state laws and ethical pronouncements on the advertising of ophthalmic goods and services. Such laws have been enacted and not declared invalid in 32 states.

*AMA* v. *Califano*—On June 2, 1978, the AMA filed a petition for a Temporary Restraining Order in the Federal District Court in Chicago to prevent the

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*Report of the AMA Board of Trustees to the House of Delegates, Interim Meeting, December, 1978.*

Secretary of HEW from releasing the names of physicians and the amounts of income generated under the Medicare program in 1977. A TRO for 10 days was granted on June 2 and then extended for another 10 days on June 12, 1978, by the Chicago Court. At the request of the Court and with the permission of the Florida Medical Association, a petition to intervene in Florida in the suit filed by FMA seeking to enjoin the Secretary was granted on June 12, 1978. The AMA has been an active participant in the litigation since June 12. FMA serves as the lead counsel in the case. The government is currently trying to appeal the Ancillary Writ of Injunction issued by the Florida District Court to the Federal Court of Appeals for the Fifth Circuit. The Secretary remains under the District Court order that prohibits his release of the list.

### II. Briefs Amicus Curiae Filed by the Office of General Counsel

The AMA has filed briefs *amicus curiae* or participated in the following suits where a successful outcome on the issues involved would be of benefit to physicians as a class:

*Shaw* v. *Hospital Authority of Cobb County, et al.*—The motion for leave of the AMA to file a brief *amicus curiae* was granted by the Federal Court of Appeals for the Fifth Circuit on April 5, 1978. The brief was filed with the concurrence of the Medical Association of Georgia to clarify the official policy statement of the AMA on hospital privileges for podiatrists. The AMA position had been mischaracterized by the American Podiatry Association. Briefs filed on behalf of Dr. Shaw, a podiatrist, had indicated that the AMA policy was based upon a report of the Board of Trustees entitled "Factors to be Considered in Granting Hospital Privileges to Qualified Podiatrists," that was filed by the House of Delegates at the 1977 Annual Convention. The official policy statement was adopted by the House of Delegates at the 1977 Interim Meeting and permits each hospital and its medical staff to determine which classes of health care practitioners shall be granted clinical privileges in accordance with community needs and applicable state laws and regulations.

*Straube* v. *Emanuel Lutheran Charity Board*—At the request of the Oregon Medical Association, a brief *amicus curiae* was filed May 26, 1978, in the Oregon Supreme Court setting forth the AMA policy statements on "due process" for physicians whose medical staff privileges have been revoked. Dr. Straube contended that he had been denied "due process" when his privileges were revoked at the Emanuel Lutheran Hospital.

*Duke Power Co., et al.* v. *Carolina Environmental Study Group, et al.*—The AMA joined the American Hospital Association in a brief *amicus curiae* filed on December 22, 1977 in the U.S. Supreme Court in a case involving the validity of legislatively established caps on tort judgments because of the importance of a favorable ruling when remedial state legislation establishing caps on malpractice awards is contested. The Supreme Court upheld the validity of caps on judgments in tort cases based on nuclear power plant mishaps.

*Madry* v. *Brevard Hospital Assoc., et al.*—At the request of the Florida Medical Association, the AMA filed a motion for leave to file a brief *amicus curiae* in support of Dr. Madry's motion for rehearing before the U.S. Supreme Court on April 10, 1978. The brief asks for a rehearing on the question of whether or not receipt of federal funds by a hospital is sufficient to establish state action for federal jurisdictional purposes. The case involves alleged deprivation of "due process" for a physician whose hospital medical staff privileges were revoked. If there is federal jurisdiction, the hospital would be required to provide "due process" in accordance with the requirements of the Fourteenth Amendment. The U.S. Supreme Court in appropriate cases grants review if the various Federal Courts of Appeal in the nine federal Circuits have conflicting opinions on a constitutional issue. On the issue of whether or not acceptance of federal funds by hospitals is sufficient to convert the hospital action to state action based on the receipt of federal and other public funds, the Circuit Courts of Appeal have conflicting opinions. Federal jurisdiction in physician-hospital dispute cases would assure application of the Fourteenth Amendment "due process" for physicians involved in such cases.

*Weisbrod* v. *Lynn*—In 1974 and 1975, the AMA filed two briefs *amicus curiae* in the Federal Court of Appeals for the District of Columbia and the U.S. Supreme Court in this case challenging the constitutionality of the mandatory retirement provisions in the Federal Civil Service Act. The validity of the retirement provisions was upheld.

*Massachusetts* v. *Murgia*—The AMA filed a brief *amicus curiae* on June 24, 1975 in this case challenging the validity of mandatory retirement at age 55 under a Massachusetts law governing employment of state highway patrolman. The validity of the provision was upheld by the U.S. Supreme Court.

Similar briefs *amicus curiae* or affidavits were filed in four additional suits challenging the validity of federal and state laws mandating retirement at age 65 or younger. The briefs set forth the policy position of the AMA opposing mandatory retirement based on chronological age. Congress has acted now to extend from age 65 to age 70 mandatory retirement for federal civil service employees.

*Bates & O'Steen* v. *State Bar of Arizona*—The AMA filed a brief *amicus curiae* on December 17, 1976 in the U.S. Supreme Court in this case challenging the right of a state bar association to establish restrictions on lawyer advertising of fees. The Supreme Court ruled that the advertising restrictions violated the First Amendment rights of lawyers, but that the antitrust laws had not been violated. The Supreme Court cited with approval a portion of the AMA Judicial Council Opinion on Advertising and Solicitation.

### III. AMA as Defendant

*FTC* v. *AMA*—On December 19, 1975, the Federal Trade Commission filed a complaint alleging that the AMA Principles of Medical Ethics insofar as they restrict physician advertising and physicians' engaging in contract practice restrain competition and result in price fixing in violation of the antitrust laws. Trial began on September 7, 1977, and was completed in May 1978. A decision from the Administrative Law Judge who heard the case was scheduled to be handed down on November 13, 1978.

The defense of this case has been vigorous and costly. The AMA has engaged in vigorous defense in order to preserve for county, state and national medical and specialty societies the right to have a role in the regulation of physician conduct. If the FTC position prevails, medical societies will be stripped of their role in the promulgation and enforcement of ethical restrictions even on misleading and deceptive advertising and the medical profession prohibited from serving any role in the self-regulation of the profession.

If the decision by the Administrative Law Judge is adverse, the AMA can appeal to the full Commission and then to the Federal Court of Appeals in one of the Circuits and then to the U.S. Supreme Court.

*Church of Scientology* v. *AMA*—The Church of Scientology filed a libel action against the AMA and the Minnesota State Medical Association in Minnesota on October 13, 1975. The suit was based on an alleged republication of libelous statements in a 1968 *Today's Health* article entitled "Scientology: Menace to Mental Health." A xerox copy of the article had been sent to a Minnesota state agency requesting information about the Church of Scientology. The suit was successfully defended and summary judgment for the defendants was granted October 19, 1976. The Scientologists appealed and the Minnesota Supreme Court affirmed the judgment on March 17, 1978.

A similar suit was filed against the AMA in a state court of Chicago on April 7, 1976. Republication of the article allegedly occurred because xerox copies had been furnished to one or more newspaper reporters. The suit was dismissed on January 24, 1977, and the judgment was affirmed by the appellate court on May 17, 1978. The Scientologists did not appeal to the Illinois Supreme Court. Defense of these cases was important in order to assure that the AMA continues to have First Amendment rights to speak out on public health issues.

*Wilk, et al.* v. *AMA, et al.*—This antitrust suit was filed by five chiropractors against the AMA and fifteen other defendants in the Federal District Court in Chicago on October 11, 1976. Discovery has proceeded vigorously with 71 depositions completed and more than 80,000 pages of documents cataloged by AMA legal counsel.

*Slavek, et al.* v. *AMA, et al.*—This antitrust suit was filed on behalf of all chiropractors licensed in the State of Pennsylvania against the AMA and eight other defendants in the Federal District Court in Philadelphia. A settlement agreement between the plaintiffs and all defendants except the Pennsylvania Society of Radiologists was preliminarily approved by the Court on May 25, 1978. The American College of Radiology was joined as a defendant in June 1978. A hearing on final approval of the settlement agreement was held September 18, 1978. The Court has not ruled on final approval of the settlement.

*Ochsner, et al.* v. *AMA*—This suit was filed in the Federal District in Philadelphia on September 15, 1978, asking to have the settlement agreement in the *Slavek* case set aside as null and void on the grounds that the AMA Board of Trustees did not have the authority to enter into it on behalf of the AMA. The suit was filed by a delegate and an alternate delegate to the AMA House of Delegates. The AMA has filed a motion to dismiss and the plaintiffs have replied. The case is before the same Judge as the *Slavek* case.

*New Jersey Chiropractic Society, et al.* v. *AMA, et al.*—This antitrust suit was filed on behalf of all chiropractors licensed in the State of New Jersey and all chiropractic patients in a New Jersey State Court on November 12, 1976. There has been extensive discovery and Dr. Sammons is to be deposed for the second time in this case on December 13 and 14, 1978. No date has been set for the trial. The cost of outside legal counsel to defend the FTC and the three antitrust suits filed by the chiropractors is now well in excess of $1,000,000.

*Diethrich* v. *AMA, et al.*—Dr. Diethrich, a cardiovascular surgeon, filed this antitrust suit February 4, 1976, against the AMA, Maricopa County Medical Society and others alleging a conspiracy to deprive him of medical society membership because of invalid restrictions on physician advertising. The suit was settled without cost or involvement in compromise by the AMA on January 23, 1978. Dr. Diethrich was one of the star witnesses for the FTC on the issues of ethical restrictions on advertising and the value to physicians of AMA membership during the trial of FTC v. AMA.

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# The Washington, D.C. PSRO Decision

**Public Citizen Health Research Group, Plaintiff**
**v.**
**Department of Health, Education, and Welfare, et al., Defendants**
**American Association of Professional Standards Review Organizations, Intervening Defendant**

**United States District Court**
**District of Columbia**

**April 25, 1978**

### Memorandum and Order

The primary issue presented by these cross-motions is whether or not defendant National Capital Medical Foundation, Inc. ("NCMF") is an "agency" for purposes of the Freedom of Information Act . . . and thus subject to the disclosure provisions of that Act. The matter has been fully briefed and argued.

Plaintiff, Public Citizen Health Research Group ("Public Citizen"), is a non-profit organization engaged in research and consumer advocacy on health and safety matters affecting Medicare and Medicaid patients in the District of Columbia. It seeks certain documents from NCMF or, alternatively, from the Department of Health, Education, and Welfare ("HEW"), a federal agency to which NCMF has certain statutory obligations, having been designated by HEW as a Professional Standards Review Organization ("PSRO"). . . .

NCMF and HEW have moved to dismiss or, alternatively, for summary judgment. They are joined by the American Association of Professional Standards Review Organizations, which was allowed to intervene as a defendant. Public Citizen has cross-moved for partial summary judgment. There are no material facts in dispute.

The PSRO program was instituted by Congress in 1972 "to promote the effective, efficient, and economical delivery of health care services of proper quality" in federally funded health care programs, most notably Medicaid and Medicare. . . . To this end, PSROs, such as defendant NCMF, are required to review health care provided to hospital patients covered by Medicaid and Medicare and to make final and binding determinations as to whether the care rendered was necessary and therefore qualified for federal reimbursement.

The origins of the PSRO program relate back to the establishment of Medicaid and Medicare. As early as 1965 Congress recognized the need to curb the delivery of unnecessary or needlessly expensive medical care in order to contain the cost of government-funded medical services. Medical services that were medically unnecessary were prohibited. . . . Because very substantial health care funds are expended for inpatient hospital care, Congress sought to assure that health care provided by institutions was necessary and of adequate quality. The statute as initially enacted only required each hospital to form its own committee of physicians to oversee and control the utilization of services provided to Medicare and Medicaid patients within their institution. . . . However, this in-house system of review failed adequately to ensure that the care rendered Medicare and Medicaid patients met statutory standards of necessity and adequate quality.

When it became apparent to Congress that these internal review procedures were inadequate, amendments to the Social Security Act were proposed to establish local and regional regulatory physicians' groups charged with the duty to make appropriate reviews. Ultimately in 1972 Congress adopted the PSRO Amendments to the Social Security Act . . . which created a comprehensive system of external monitoring of hospital-based health care delivery by PSROs. The Secretary of HEW was

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*EDITOR'S NOTE: All legal citations have been deleted.*

required to establish areas throughout the country within which PSROs would be designated. As soon thereafter as practicable, the Secretary was required to designate a qualified organization within each area as the PSRO. . . .

Federally designated PSROs such as NCMF operate under contract with HEW. In addition to other functions, they review the professional services rendered by practitioners and providers in their area to determine: (1) whether certain institutionally based services are medically necessary; (2) whether such services are of acceptable quality; and (3) whether appropriate care could be provided as effectively on an outpatient basis or more economically in a different type of inpatient facility. The purpose of these reviews is to determine if the services rendered were delivered in conformance with the applicable criteria. Reviews conducted by PSROs are relatively standardized, since all PSRO reviews must be based on regional norms of medical practice established for that area.

Under a system established by HEW, members of a PSRO routinely review Medicaid and Medicare patients in hospitals within the PSRO's jurisdiction. According to HEW requirements, PSROs must undertake four stages of review: (1) admission certification, (2) continued stay review, (3) medical care evaluation studies, and (4) profile analysis. HEW, PSRO Program Manual. . . .

Admission certification review concerns the medical necessity of hospital admissions. PSRO members generally review an admission during the first day of hospital stay to determine whether the patient needs to be hospitalized at all. Based on that review, members predict, or "assign," the appropriate length of the patient's stay. . . .

Continued stay reviews are conducted for patients who remain in the hospital beyond the expiration of their predicted stay. These reviews are made to determine whether continued hospitalization is in fact needed. Additional days may be assigned at this time, or, in the event that the PSRO concludes the additional stay is not "medically necessary," the PSRO can disapprove of continued hospitalization. . . . In that event, once the patient has been notified that the PSRO deems his additional stay to be medically unnecessary, the patient must thereafter either leave the hospital or make private payment. . . .

The PSRO statute provides that PSRO determinations with regard to the medical necessity, conformance to professional standards, and appropriateness of institutional setting of admissions and continued stays "shall constitute the *conclusive* determination of those issues . . . for purposes of payment under this Act." Medicare-Medicaid Antifraud and Abuse Amendments . . . (emphasis added). Reconsideration and eventual appeal of PSRO decisions to HEW is provided for by the PSRO statute under certain limited circumstances if the PSRO determination is adverse. However, favorable determinations by the PSRO as to medical necessity are binding on the payors and are never reviewed by HEW because they are not appealable. Indeed, the statute requires notice only of adverse PSRO determinations. All PSRO approvals are therefore final and binding on HEW. Approximately one percent of the hospital patients reviewed by NCMF during the first year of operation made claims which were disapproved. Thus, in nearly 99% of NCMF's cases, there was no possibility that the Secretary of HEW could review NCMF's decision of medical necessity.

Once a PSRO determines medical necessity, conformance to professional standards, and appropriateness of institutional setting, other matters in the exclusive province of HEW must be resolved. PSROs do not determine eligibility under the programs, coverage, or the reasonableness of charges. Yet the fact remains that in practically all cases benefits are not paid unless the PSRO makes its conclusive affirmative determinations of medical necessity.

In addition, of course, PSROs perform a variety of significant independent decisional functions supplementing the overall governmental program, such as evaluating care rendered groups of patients in respect to specific medical problems within HEW guidelines, developing criteria, and collecting data for governmental purposes. PSROs also perform profile analysis of individual doctors or hospitals to detect patterns of abuse and substandard care.

NCMF urges that it should not be treated as an "agency" for purposes of the Freedom of Information Act because of the following factors:

(1) Its relations with HEW are contractual.
(2) It was not established by federal law.
(3) Its employees are not civil servants or protected by the Federal Tort Claims Act.
(4) Its activities are largely advisory to HEW in its performance of what are essentially peer group monitoring functions.
(5) Most of its decisions are not binding.
(6) It is free to, and in fact does contract to perform various functions for state and city agencies and for private parties.
(7) HEW supervision is accomplished by regulations, not day-to-day control.

Thus NCMF presents itself in the guise of a consultant and points to the obvious fact that the Secretary of HEW is the person charged with ultimate responsibility for implementing the congressional purpose.

Whether or not NCMF is subject to the Freedom of Information Act depends on whether or not it fits the generalized definition of agency found in the

Administrative Procedure Act ("APA"), *i.e.*, an "authority of the Government of the United States, whether or not it is within and subject to review by another agency. . . . " In *Washington Research Project, Inc.* v. *Department of HEW* . . . the Court took cognizance of the varying arrangements Congress has designed for implementing governmental functions through private or quasi-private entities. Recognizing the "myriad organizational arrangements" adopted "for getting the business of government done," it was forced to the "unavoidable fact" that each arrangement must be examined in its own context to determine whether or not it constitutes an "agency" within the term agency as defined in the APA.

The Court held that while all factors must be weighed, "the important consideration is whether it has any authority in law to make decisions." As previously explained, NCMF has such authority and exercises it daily. Given this undisputable fact, which alone may be decisive, it also plays a crucial role requiring exercise of its independent decisional authority. These significant factors weigh heavily in this context. NCMF is financed by the United States, it is a creature of statute, it performs an executive function, and it operates under direct, pervasive, continuous regulatory control affecting even minutia of the procedures and functions. . . .

Considerable emphasis is placed on the undisputable fact that Congress sought to protect PSROs by statutory provisions designed to assure substantial confidentiality of their working records. Since, however, the Secretary of HEW retained discretionary authority over release of PSRO data and no flat exemption from the FOIA was enacted, these confidentiality provisions give way to FOIA standards. . . .

The Court is well aware that the affidavits and attitudes of the medical profession strongly suggest that the peer review mechanism which Congress wisely established in enacting the PSRO program will experience a severe setback, if not fatal blow, should PSRO records become generally available through the FOIA. But the remedy for alleviating these justifiable concerns lies with Congress, not the courts.

Since NCMF must be deemed an agency, it alone is required to respond to plaintiff under the FOIA. At this juncture there has been no determination as to whether some or all of the documents sought are protected from disclosure by NCMF under the various statutory exemptions set out in the FOIA. This process must now be set into motion by remanding to NCMF for determination. While HEW has neither possession nor control of the records sought, its administrative processes for processing the request can and perhaps should be used and accordingly its motion to dismiss will not be granted.

Plaintiff's motion for partial summary judgment is granted, defendants' motions to dismiss are denied, and the case is remanded to NCMF and HEW for prompt processing of the plaintiff's FOIA request.

SO ORDERED.

Gerhard A. Gesell
*United States District Judge*

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# The President's Page

## Thoughts on Our Profession's Weaknesses

In his essay, "The Melancholy Herd—Further Thoughts on the American Bedouin" in the July 1978 issue of *Harper's* magazine, Lewis H. Lapham described the patrician, decision-making classes of our society as dwelling in an "interior desert of alienation." "Knowing nothing of history and expecting nothing of the future, they cannot escape the fearful isolation of the present." Describing the upheavals of the 1960's he continued, "Stopping up their loneliness with frenzied expressions of faith (in the environment, black power, civil rights, feminism, peace in Asia, Consciousness III, et cetera), the bedouin proclaimed a Jihad against the institutions that provided them with their patrimony." These patricians, he concluded, are "people who decide what lesser people will do, who supervise the manufacture of memoranda, rather than goods." "They have inherited," he wrote, "the stewardship of the principal American institutions without knowing what constitutes the burden of their authority, or whence it comes, or what it cost their forefathers." They reminded him of the French aristocrats who supported the philosophical ideas that shortly led to revolution and for many of them, to the guillotine.

The October 1978 *Harper's* magazine contained a fascinating exposition, "The Professions Under Siege," by Professor Jacques Barzun. Quoting him, "As for the scientists, demigods since Darwin, they became objects of suspicion after Hiroshima. Their work was amoral; they dabbled in treason and warmongering, and in any case, their view of the universe was probably at the root of the modern malaise." Later he quoted a letter to the *New York Times* from an affirmative action officer of an eastern university, explaining the "rising popular discontent with the so-called truths of all disciplines and the so-called standard practices of all professions" as "resulting from the limited vision of those who control these areas of human thought and endeavor."

Earlier, in the May 25, 1978 issue of *The New England Journal of Medicine,* there had appeared "How to Fix the Premedical Curriculum" by Dr. Lewis Thomas, a former Dean of the Yale School of Medicine. Wrote he, "They (the students) concentrate on sciences with a fury. . . . If there are courses in humanities that can be taken without risk to class standing, they will line up for them. . . . The atmosphere of the liberal arts college is being poisoned by premedical students. . . . They behave as they do in the firm belief that if they behave in any other way they won't get into medical school." He makes his recommendations which you should re-read and concludes, "We could look forward to a generation of doctors who have learned as much as anyone can learn . . . about how human beings have always lived out their lives. Over the bedrock of knowledge about our civilization, the medical schools could then construct as solid a structure of medical science as can be built, but the bedrock would always be there, holding everything else upright."

I have cogitated on these three expositions, varied in thrust and authorship. I find them at once upsetting and reassuring. I find my colleagues technically capable, scientifically well trained and usually expert technicians. But they are also too often inadequate historians, philosophers and ethicists. They translate their scientific knowledge and the decisions flowing from it poorly to their patients. They cannot speak or write literately for either medical or lay audiences. They are unwilling to expose their inadequacies to each other, let alone to the public. And many are oriented overmuch to monetary goals. In brief, they are the expected products of the system created by the intellectual leaders of our profession, the academics. This system has emphasized science to the point of harm to the public good. How, you may well ask, can one be too expert technically? "Never," I would answer. But I would commend to you Barzun's quote of Dr. Abraham Flexner, fifty years ago, defining the profession of medicine as "the possession of certain portions of many sciences arranged and organized with a distinct practical purpose in view. That is what makes it a profession."

I ask then what kind of an inadequate system we have created where medicine can no longer be made understandable to nonscientists? While assuring their expertise in technical area, we have failed to similarly assure physicians' adequacy in Dr. Thomas' "bedrock of knowledge about our civilization." Both of Connecticut's medical schools share this blame, Yale far more than the University of Connecticut, as it is far older and as yet more prestigious nationally. During both my undergraduate days at Yale and in my surgical interneship there it was very common knowledge that its medical school trained researchers and teachers as opposed to practitioners. From personal experience of some length, I accuse academic medicine of undervaluing liberal education and background both in its students and faculties.

It is time for a revolution in our profession. We must be willing and able to explain what we do to the public. The public does, after all, have the right to know. We must be willing to talk publicly of the ethical implications for the patient, of blindly zealous cost controls as advocated by governmental and quasi-governmental bodies. We must be willing to translate the arcane language of SHCC, CHHC, and HEW into the practical equivalents of rationing and denials of service. We have to place before the public facts such as the ten thousand intentional and preventible deaths each year in England, because an administrative decision resulted in insufficient renal dialysis machines to prevent them.

When we are faced with a matter such as the recent proposed order of the FTC, we must be willing to go public about the dangers we think are inherent for the public. The Council's and Legal Counsel's timidities about the possibility of errors being made in public should perhaps be overruled. Maybe we also dwell "in an interior desert of alienation." The leaderships of academic and community medicine must begin to work together to clean house in their respective areas. The system must be reformed to produce educated people who practice medicine rather than technicians who practice science. Until we do these things, there will, I fear, continue to be difficulties between town and gown; there will continue to be too many departmental chairmen who are poor role models for their students; there will continue to be ineffectiveness in dealing with our impaired and/or inadequate colleagues. There is much to do. We in the state medical society are taking the first hesitant steps to deal with these problems. We have a long way to go and there are organizational and intellectual changes that we still need to make. There will be no possibility of success without the help of academic and non-academic physicians.

Jerome K. Freedman, M.D.
*President*

# Reflections from the Dean's Office

## No Requirements, Please!

ROBERT U. MASSEY, M.D.

After finding a new book or discovering an old one, some friend or colleague is often anxious to tell me that every medical student should be required to read it. Except for making it a requirement, I generally agree. Most of us could make a list of works which physicians should read; our lists would not be the same, and we should probably find that we had read only a handful of those on anyone's list, even our own. Osler had his list of ten which he called a bedside library which included the Bible and all of Shakespeare, but he left out Dante, most of the poets, and all of the moderns except Holmes.

When someone declares that a book or play should be required reading for medical students, he must believe that the author has come upon some new truth that physicians especially ought to know. Perhaps in his experience doctors are blind to that truth, and he is persuaded that their patients would benefit if that blindness could only be removed. In most people's view physicians know a great number of facts about science and technology, but neglect other kinds of truth, or may have neither the wit nor the time for them.

That is an old reproach, and portrayals of physicians as single-minded technicians hiding behind incomprehensible systems are as ancient as any literary tradition. George Bernard Shaw's *The Doctor's Dilemma* is one of the better modern works on this theme. Of course, every medical student ought to read it! Shaw called it a tragedy, and whether the tragedy is medicine's failure to achieve greatness even with the help of modern science, or the moral decline of Sir Colenso Ridgeon, or the unmoving death of the artist, Louis Dubedat, is up to the reader to decide.

There are doctors in books and books by doctors; there is more in novels about medicine and society than the sociologists have dreamed of. There is more written about sickness and death than about doctors, and in all these stories there are truths that cannot be expressed as well, or even expressed at all, in the language of science. Although psychiatrists may have known this, the behavioral scientists seem often about to discover what Chaucer thought everyone knew.

While some things we know by immediate experience, most of what we know, or will ever learn, is by analogy, by relating a new observation to an older experience, by imagining a story. "Then began he to speak to the people this parable." (Luke 20:9) There are finespun psychological and literary theories about the place of myth in understanding the world, and obscure philosophical theories about the relation of illusion to reality. Fortunately we do not have to comprehend these to enjoy a good tale or to be grateful to the author for showing us a new truth. Whether creativity in the writer is different from creativity in the scientist is less important to know than that each has a special and equally authentic understanding of the truth. Matthew Arnold made the observation that if the aim is "to know ourselves and the world, we have, as the means to this end, to know the best which has been thought and said in the world." He later explained that his phrase encompassed science, literature, and art.[1]

Arthur Schnitzler, the turn-of-the-century Viennese otolaryngologist, wrote *Novellen* and plays with a deceptively light touch, which nevertheless showed his full understanding of the theories of his friend Sigmund Freud. In *Sterben,* the story of a young writer dying of tuberculosis, there is acceptance and denial, grief and rage, which we only recently have discovered about death and dying. There is a specialist who feels compelled by the patient to tell the truth: "I must have certainty"; a physician-friend who wants desperately to share in his patient's delusions of ultimate recovery; and there is a hint of the doctor's dilemma, although Schnitzler's *Novelle* is 20 years earlier than Shaw's play. Every medical student ought to read it! And then follow it with Thomas Mann's *Magic Mountain.* And then Chekov. The list grows longer; a lifetime is not enough to come to the end of it.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

**Connecticut Medicine**

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# EDITORIALS

## Privacy versus Freedom of Information: The Washington, D.C. PSRO Decision

On April 25, 1978 Judge Gerhard A. Gesell in the U.S. District Court for the District of Columbia ruled that the National Capital Medical Foundation (NCMF), a PSRO, is subject to the provisions of the Freedom of Information Act (FOIA).[1] The Public Citizen Health Research Group (Public Citizen), a research and consumer advocacy organization on health and safety matters affecting Medicaid and Medicare patients in Washington, D.C., sought certain documents from NCMF or DHEW under the Freedom of Information Act. The PSRO argued that it was not an agency since its relations with DHEW were contractual, that it was not established by federal law, its employees were not civil servants, and it performed functions for other government agencies and for private parties. But the court disagreed, claiming that the PSRO was an agency for FOIA purposes since it was financed by the U.S., performed an executive function and operated under direct and pervasive regulatory control.

Judge Gesell wrote that the court was aware the peer review mechanism established by Congress in enacting the PSRO program might experience a severe setback, if not a fatal blow, should PSRO records become generally available through the FOIA. He suggested that the remedy for alleviating these justifiable concerns lies with Congress and not the courts.

The trial court decision has stirred fears throughout the medical community that the NCHF PSRO case will lead public-interest groups across the nation to challenge their local PSRO's, based upon Gesell. Rumors abounded that the consumer advocacy groups were in full cry, headed for litigation. But there has not been an additional court case brought in the nation, according to DHEW officials who monitor PSRO's. Since there is no reporting system for such cases, this information may not be wholly reliable. Even though the Gesell decision specifically applies to the NCMF PSRO, physicians are concerned that it may set a precedent for district courts elsewhere in the country.

Public Citizen is apparently not seeking patient records but wants doctor information which would reveal relative admissions rates, lengths of stay and adverse PSRO determinations, for purposes of public education. The group's specific requests do not appear in the court decision but physicians assume that the disclosure of these data was the motivation for the suit. Doctors recall with resentment that when the Bennett Amendment to the Social Security Act was debated by the Congress in 1972, legislators and DHEW officials allayed their concerns by pledging that PSRO record privacy would be maintained.

Gesell's decision did not address at all the breakdown of informational categories in PSRO data collections but only dealt with the question of whether NCMF was an agency for purposes of the FOIA. Presently, NCMF and Public Citizen are jointly reviewing the data collection and the citizen advocates will then tell Judge Gesell what they require. The judge will compare these requests with the provisions of the FOIA and its exemptions. If the information requested cannot be protected under the FOIA, an appeal will follow. Judge Gessell will not order the requested information to be turned over to Public Citizen, prior to an appellate decision.

Physicians' concerns lie largely in the medical audit area. If this material were subject to discovery, local problems such as high ECT usage or high O.R. infection rates could contribute to legal actions mounted against hospitals or doctors. Lawyers do not usually seek medical audit data because hospitals have long been protected by state laws barring disclosure.

Judge Gesell's recommendation for legislative remediation spurred Senator Richard Schweiker (R., Pa.) to introduce an amendment to the Social Security Act. This initiative failed because Senator James Abourezk (D., S.D.) opposed it. As chairman of a Senate Sub-committee which dealt with the FOIA, he wished to limit any further exemptions to that law. The Schweiker bill became caught in the end of session logjam and no compromises were possible. Abourezk has since retired but so has Representative Paul Rogers (D., Fla.), chairman of the House Health Subcommittee, who together with Representative Tim Carter (R., Ky.) sponsored the counterpart to Schweiker's bill in the House. The sentiments of the future and unknown replacement of Rogers in the 96th Congress may determine what happens to remedial legislation.

Apart from the legislative pathway for amending the PSRO provisions of the Social Security Act, another route for privacy protections exists in the FOIA exemptions. Many scholars of government would argue that the FOIA exemption route is generally better for the workings of the political process than seeking legislative relief. An FOIA exemption states that if a law pre-exists which protects information, it would supersede the FOIA provisions. Such pre-existent statutes are found in Social Security Act Section 1166, Title XI, Part B (also found as 42 USC §1320 e-15) which defines disclosure and exemptions in PSRO's. DHEW, which supports exempting PSRO's from the FOIA, has been preparing disclosure regulations for PSRO statutes. Skeptical Department officials speculate that they may be published in six weeks or six months depending upon their treatment in the laborious internal review. As currently drafted, their contents would protect patient information, physician information and medical care evaluation studies. It is possible that a future court challenge might decide that the FOIA supersedes Section 1166. Subsection (b) of 1166 provides for disclosure for the purpose of investigating fraud or abuse and implementing health care planning in accordance with procedures set by the Secretary of DHEW. The FOIA was amended in the Government In The Sunshine Act, PL94-409 on September 13, 1976. Section (5b) raises the concern of Congress about the exemptions in other statutes (as in 1166) stipulated by the discretionary power of the Secretary of DHEW (in the case of Section 1166). Congress attempted to establish standards of definiteness for pre-existent statutes impinging on the FOIA. The question, which may have to be court-decided, is whether or not 1166 is sufficiently definite to exempt PSRO's from the FOIA.

Another argument might be made, albeit a unique one, to protect the privacy of records through an existent FOIA exemption. Profit-making organizations under a trade secret exemption in the FOIA are not required to reveal their records if, for instance, they submit proposals for a contract to the NIMH. The courts have not said that a non-profit making organization (a hospital or PSRO) may keep "trade secrets" so the question remains to be settled.

There are some PSRO's operating in the private sector—a few associated with labor unions. Judge Gesell's decision applies only to federally affiliated PSRO's, thus the private sector organizations are not subject to the FOIA or PSRO regulations. The latter are protected by a hodge-podge of state laws across the nation. DHEW is developing model state laws to protect PSRO privacy in the private sector but can only recommend their consideration for adoption by the states.

At this writing, the complex legal situation in the District Court for the District of Columbia is moving at a snail's pace. It is possible that the wrangle will be settled by the 96th Congress before the emergence of a judicial solution.

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## Let's Play the Health Game: The Doctor Is OK Today

In a previous communication a point of view was expressed that the present nervous status of the entire Health Scene results from a rapidly expanding geopolitical base and technology. The result is an overgrowth of the old Family Doctor as the all-in-one Health deliverer and the creation of pockets of vacuum within the delivery system mandating new jobs and disciplines to bridge the islands and provide correlative pathways for health delivery. The problem is compounded by the expanded therapeutic armamentarium and aggravated by the general societal inflation of cost of materiel and labor. The control over the health of people during this century has passed from the hands of the Doctor into the hands of the Politicians and Bureaucrats. The excuse of the latter has been that the doctor is obviously at fault, derelict and incompetent; the Doctor has been thrown into the pockets of vacuum to no avail, which has only "proven the case against the Doctor."

Today, the teaching game is to reverse the roles. Assuming that the Doctor is OK today, the game problem is to explain how the present state of affairs could have occurred. The first step in the game is "neutralize" those now in control: the Bureaucrats. Throughout the pages of recorded history, man has been plagued by the self-serving Bureaucrat,* and in the present century many feel that history is not repeating itself in this respect, but simply continues unchanged. It is human nature to attempt credit for good things but to project shortcomings upon others. Beware the Bureaucrat who projects "self-serving" upon others; beware the Bureaucrat's base of projection. To complete the first step: No man can serve two masters, because he will serve the one and despise the other. He who serves himself as a master (the state of self-serving) is a slave to his own blind ego and will be in dire straits on the day of reckoning when he will truly have only himself to blame.

The second step in this executive game is resuscitate the image of Doctor. While these societal changes have been occurring the doctor first noted he was no longer able to control the expanding health system; it was the doctor who gave birth to the hospital administrator, to various other health planners while he himself was more than occupied by attempting to keep up with all the technicological advances in diagnosis and therapeutics which his patients have been demanding in increasing scope and intensity. The rapid expansion of health needs has created pockets of vacuum which have been filled by all sorts of make-shift programs and creatures because "nature (and all its creatures) abhors a vacuum." Not all of the vacuum-filled debris was functional or efficient, which is understandable in that innovations were called for and these areas could not be functionally filled by traditional-thinking Doctors nor, much less, by the Bureaucrats who became sucked into the vacuum while snooping around. Political hay was made by blaming the poor Doctor for escalating costs and inefficiency, thus placing the Doctor out of control and the Bureaucrat into control. The poor doctor, already overwhelmed by the exploding medical technology, and, now defensive against the political incriminations, simply had no reserves left to attempt correction of the delivery system: the carpet baggers moved in and are now making their political Brownie points.

The third step in this teaching game is to define the present system "as it is." No one really questions the need to change the health delivery system. Everyone has a share, and it seems a voice in this system. But any system where the primary deliverer of health services, who must train from eleven to fifteen years post secondary education, is manipulated and controlled by sharpies with far less training and study, is bound to suffer drastically from reduction in the quality of service, and thereby or perhaps more directly, fail outright.

The final step of our executive teaching game is to elaborate the formula for success, keeping in mind that the formula is also the therapy for the Bureaucrat. Surround me with men who admit their own faults and the good work of others. There certainly is a place for men of vision who can see beyond their fellowman, but let them not overlook the nearby things and people because they are so close as to be out of focus. Because we can detect that the health care system will evolve into a totally hospital-based system with hospital salaried staff, is no justification for attempting the immediate implementation of the inevitable. Although someone always suffers from progress, existing systems of private practice should not be summarily threatened because lifetimes of training, service and family welfares are at stake. Indeed, if one recognizes the eventual, such will inevitably occur if gently nourished as the present generation dies off, and the newer generation of Doctors, imbued with the changing needs of service to society, take hold and create an improved health delivery system. The slogan: "Bureaucrats, back off and let it happen."

Adam Wesolow, M.D.

*Chairman, Dept. of Surgery*
*The Hospital of St. Raphael*

*References: The Bible; Taylor Caldwell; Congressional Investigations.

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## The Physician and the Abused Child

Child abuse and neglect account for a significant degree of infant and childhood morbidity and mortality. Child maltreatment in this country is now the second most common cause of death in children after the perinatal period—second only to the sudden infant death syndrome in infancy, and second to accidents in older children.

Nationwide child abuse statistics are notoriously inaccurate because of deficiencies and irregularities in reporting in the various states. In Connecticut, in the first 10 months of 1978, over 9,000 cases of child abuse/neglect (including sexual abuse) were reported to Protective Services of the Division of Children and Youth Services (DCYS). There were at least 12 deaths.[1]

David L. Kerns has concisely summarized in this issue of *Connecticut Medicine* the Connecticut physician's role in identifying children who are suspected of being maltreated, and his subsequent legal and ethical responsibility to make a report to the authorized child protection agency. Although in the past failure to identify and report suspected cases might have been due to a physician's inadequate medical school education and house staff training in the child maltreatment syndrome, in Connecticut at least, that situation is being rectified. Pediatric departments of both medical schools in the state include lectures and discussions of child abuse in the curriculum, and in the last five years numerous community hospitals have developed multidisciplinary child protection teams to review suspected cases and to insure accurate reporting to local DCYS offices.

A number of significant problems still remain, however, which operate against physician involvement in these difficult cases. Dr. Kerns warns against falling into a "common error," the "tendency to be too investigative"—and yet, a physician at a community hospital without an active social service department or child protection team indeed must gather as much data as possible, or risk loss of credibility when he testifies before the opposing lawyer or the juvenile court judge.

And as Kerns said, the price of involvement *is* high. A concerned physician subpoenaed to juvenile court may have to cancel a half day's patients. He may find himself interviewed by an assistant attorney general who is himself unfamiliar with the case, for the burden of collecting and preparing evidence for the juvenile court is borne largely by the overworked Protective Services workers. And after waiting many hours while other more urgent cases are heard, he may be told that the case has been postponed to another day. It's not hard to see why physicians, except in the most certain and obvious cases of child abuse, are reluctant to brave our present legal system.

More Protective Services workers have been hired in this state in recent months in an attempt to meet the rapidly increasing demand and to reduce the enormous case loads. But because of the case loads and the difficulties of working with often hostile parents, the Protective Services workers have only a limited therapeutic role. As Dr. Kerns suggests, other therapeutic services may be available to families in crisis, but many inadequacies exist. Excellent therapeutic foster homes are too few in number, and good day care facilities for disturbed children are for the most part filled. The successful Parent Aide Program in New Haven, for example, which is supported by a unique combination of public (CETA) and private funds, is oversubscribed, and abusing families must be put on a "waiting list."

These problems are not unique to Connecticut but are recognized by child abuse workers in every state. Physicians and others bear a responsibility for reporting suspected cases of maltreatment, but likewise state legislators and agencies have a responsibility to appropriate funds and to staff programs for the meaningful rehabilitation of abusing families.

What other roles can the primary physician have in child abuse? Perhaps, as Dr. Kerns suggests, primary physicians who identify child maltreatment can make referrals to multidisciplinary teams and "subspecialists" in child abuse, or they can serve on such multidisciplinary teams themselves. Ideally such families should not be referred out of town but should remain in the care of the primary physician. The "subspecialist" can be consulted, but the primary physician can, over an extended period of time, offer the family the kind of nurture and support that may, along with other modes of therapy, change their pattern of child-rearing to a more healthful one.

I wholeheartedly agree with Dr. Kerns that despite serious obstacles, physicians must identify and report abusive families in order to offer them help. But the responsibility for *caring* about children rests not only with physicians, but at all levels of our legal and social system.

Carole A. Stashwick, M.D.
*Assistant Professor of Pediatrics*
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# Letters to the Editor

**Letters to the Editor are welcomed and will be published, if found suitable, as space permits. Like other material submitted for publication, they must be typewritten *double spaced* (including references), must not exceed 1½ pages in length and will be subject to editing and possible abridgment.**

### DHEW SURVEY VOLUNTARY?

*To the Editor: (For your information the following letter was sent to Dr. Douglas Lloyd, Commissioner, State Department of Health, Hartford).*

Upon opening mail from your Department, I found the license renewal form "Statistical Data Card-MD" and a cover letter briefly explaining that your Department has joined the Cooperative Health Statistics System (CHSS) of the National Center for Health Statistics of DHEW. Also enclosed was "Statistical Survey" Physicians and Surgeons. CHSS-1-New 11/78."

I was astonished by the contents of the "Statistical Survey" considering the impact of the Federal Privacy Act of 1974 and the discussions with your Department following the enactment of the Connecticut Confidentiality Act more than two years ago. Beyond the minimal data required for relicensure, it asks for racial, marital data, questions about Spanish origin, principal form of present employment, hours per week in present activities, principal settings where one works and whether one has received training in physical disabilities, developmental disorders or alcoholism. In addition, it requests the physician's Social Security number. Since none of this personal information is apparently required by law for the mission of your Department, your inquiry constitutes an invasion of privacy.

There was nothing in your cover letter to suggest that completion of the questionnaire is voluntary and that failure to participate will not result in a penalty. In fact, enclosing such a questionnaire in a medical license renewal letter recommends to most colleagues that the questionnaire is clearly associated with license renewal procedures. Further, we are not told which of the elements, if any, of the collected data are actually required for relicensure by statute or regulation, and which collected material will be treated as confidential. Will the CHSS use individual names at the federal level? Why do you need Social Security numbers, if not for identifiers on the "Statistical Survey" form, and why indeed, do you need Social Security numbers on the licensure renewal card "Statistical Data Card-MD" when you already have our Connecticut registration numbers? On the CHSS form, will data be aggregated or will it be circulated to other federal agencies and divisions within DHEW in a non-aggregate form together with identifiers? How will such data be managed within the State Department of Health from the standpoint of confidentiality and information security? What linkages exist for the transmittal of information collected in your Department and other departments in the State government, and health departments of other state governments? Will the data be available to the Connecticut State Medical Society, to planning, policy and manpower groupings in government or with government affiliations?

The character of your inquiry is a threat to confidentiality safeguards painfully arrived at on state and federal levels. I would prefer to believe that our most senior medical colleague in the Connecticut State government nodded, like Homer, and that your inquiry was only an oversight with conceivably unfortunate consequences.

You can redress the potential harm by announcing through the Connecticut State Medical Society that the collected material requested on the CHSS forms will be destroyed, and that Social Security numbers will be erased from the "Statistical Data Card-MD" and not requested again in the years to come. If you need data for the CHSS, then you should mail your request out once more, with a cover letter citing *in detail* the applicable confidentiality safeguards, and whether or not a response from the physician is mandatory by statute.

The Connecticut Psychiatric Society will immediately instruct its members who have not yet mailed the CHSS form to the Department of Health, not to do so until these questions are satisfactorily answered.

Herbert S. Sacks, M.D.

*Clinical Professor of Pediatrics*
*and Psychiatry*
*Yale University School of Medicine*

*Dr. Sacks is a member of the Executive Committee of the Board of Directors of the National Commission on Confidentiality of the Health Record.*

---

EDITOR'S NOTE: The following is a motion adopted by the Council at its January 10th, 1979 meeting: "It was VOTED that CSMS Staff should direct a communication to Commissioner Lloyd objecting to the Statistical Survey accompanying the license renewal form which should have indicated its voluntary nature and that physicians were not required to complete it."

## THE DOCTOR'S IMAGE

*To the Editor:* A brochure arrived at my desk not long ago from a firm that markets sundry items for physicians. You may recall receiving these booklets from time to time. On the cover is a tennis racquet, calculator and elegant set of car keys, lying across a recent issue of *The Wall Street Journal.* Items in the catalogue include medical supplies, instruments and furniture, but substantial space is given to luxury motorcars, powerboats and such specialized items of self-indulgence as a solid brass replica of a railroad locomotive in a showcase, for $400.00.

This catalogue itself is handsomely designed with tear-out post cards to order the merchandise at minimum inconvenience (with boxes to designate one of three major credit cards). A special feature of this most recent mailing is an 8-page insert of jewelry ranging in price from about $30.00 to $16,500.00 (marked down from $24,750.00).

Now, no matter what we may think of our worth to society and no matter how spartan we feel as we fish up the college tuitions and confront the real costs involved in taking care of overhead in our practices, raising our families and keeping pace with the cost of living, we must realize that a good many entrepreneurs view us as a bonanza for luxury dollars. At least the firm whose catalogue I have described has stayed in business a number of years on this premise.

An ad appeared a few months back in this very Journal (for office insurance if I recall correctly). The automobile used as an eyecatcher for this service was a Rolls Royce. The ad agency may have been aiming at the Rolls Royce set, but I rather imagine their real mark was those of us who aspire to that kind of status.

One of our national liberal political journals has been taking broadside swipes at the medical profession for demanding and getting an income they deem disproportionate to our values to society. I believe they are indulging in a bias produced by the fact that while a few personality journalists can demand and get $1,000,000 a year, most are poorly paid (though not necessarily underpaid).

Pay in other professions, however, cannot be used as an excuse for us. We are in a position of special responsibility to the people we serve, and for this reason can easily be perceived as taking more from the system than we are worth. Many of my colleagues defend conspicuous consumption by claiming that their patients demand it and are impressed by it. For some, no doubt, this is still true, but growing numbers are finding our material success irritating and conclude that it is undeserved.

Moreover, we have a lot to answer for as we compare the early attainment of affluence by our young specialists with the lives of their doughty forebears who plugged along over the years, often content with barter for payment or resigned to no payment at all.

I happen to think our value to society is underrated almost everywhere outside the profession itself these days. Whether it is or not, no amount of protest or self-justification will protect us if we do not make an honest effort to maintain and enhance our true value to society. It would be the worst perversion of all if we tried to improve our image without improving ourselves. There is a pernicious custom in our market economy for manufacturers to work harder on the *image* of quality in their products than they do on the quality. We must not get caught in that trap nor should we be beguiled into thinking of health care as a marketable product.

We are professionals responding to the most fundamental needs of our society. We must protect our good name by curbing excesses in ourselves and our colleagues. Since, unfortunately, it is just as necessary to seem right as it is to be right, we must also convince our fellow citizens that we are guided by the best motives. Cutting our prospective *increases* by 1% as proposed last summer by the new AMA President will be pretty weak tea in this effort.

We must concentrate on service and self-discipline. The image will take care of itself.

John L. Meyer, II, M.D.

# FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511
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*Associate Executive Director*

Robert J. Brunell
*Assistant Executive Director*
*Scientific Activities*

## Council Meeting

Wednesday, December 13, 1978
160 St. Ronan Street, New Haven, Conn.

### Attendance

Present were: Drs. Freedman, Kamens, James, Backhus, Spitz, Ragland, Jr., Friedberg, Hess, Fabro, Canzonetti, Cramer, Van Syckle, McGarry, Sadowski, Anderson, Magram, Zlotsky, Whalen, Beck, Rosenthal, J. Barrett, Parrella, Tierney, Sonnen and Bates.

Also present: Mr. Tomat (FCMA), Mrs. Lindquist, Mr. Sweeney, Mr. Brunell and Mr. Norbeck.

### Approval of Minutes

It was VOTED to approve the minutes of the meeting of September 28, which were distributed prior to the House of Delegates meeting.

### Introduction of New Associate Councilors

Dr. Canzonetti introduced the following new Associate Councilors:

Litchfield County:

John J. Barrett, Torrington—replacing Robert Harkins, Woodbury.

Windham County:

David H. Bates, Putnam—replacing William M. Shepard, Putnam.

### Committee on Perinatal Morbidity & Mortality

It was VOTED to clarify the fact that the Committee on Perinatal Morbidity and Mortality is a standing committee for the purpose of medical review.

### President's Report

President Freedman reported on his activities since the past Council meeting which included a luncheon with Deans Massey and Heinz of the University of Connecticut and Yale Medical School, respectively, on the subject of CME. He mentioned that tort reform in California was the main topic of discussion at the recently concluded meeting of the Organization of State Medical Association Presidents.

The President also apprised the Council of a letter received from the Department of Aging which requested a representative from CSMS to serve on Department sponsored Committee for a Better Medicine Assignment Rate. It was VOTED to authorize the Chairman of the Council and President to appoint a member to the committee. Subsequently, Dr. Irving I. Rosenthal, Bloomfield, was appointed.

Dr. Freedman discussed an issue relating to complaints heard from physicians concerning their disagreements with the Department of Social Services over the coding system used for payments. After discussion, it was VOTED to send a letter to all complainants, pointing out the avenues available to them for fair disposition of the matter, and informing the physicians that they may submit the issue to the CSMS Committee on Peer Review Systems after exhausting those options. It was pointed out during the discussion that the CSMS Liaison Committee with the State Department of Social Services had held several meetings with the Department over this matter and had effected some positive changes. Mr. Steve Press, executive director of the Department, has indicated his willingness to discuss any individual problem situation with the physician involved.

### Fiscal Items

(a) *Meeting of AMA Representatives:* It was VOTED to reimburse Jerome K. Freedman, M.D., in the amount of $65.54 for a dinner meeting held with AMA representatives.

(b) *Council of New England Medical Societies, 10/7/78:* It was VOTED to reimburse J. Alfred Fabro, M.D. and Jerome K. Freedman, M.D. in the amounts of $44.10 and $51.30, respectively, for expenses incurred at the subject meeting.

(c) *Delegate to the Annual Meeting of the Main Medical Association:* It was VOTED to reimburse W. Raymond James, M.D., for expenses incurred while attending the subject meeting.

(d) *Committee to Study Perinatal Morbidity and Mortality:* It was VOTED to authorize $250 in addition to the $500 already allocated to the subject committee to help finance its Perinatal Seminar.

(e) *Purchase of Office Equipment:* It was VOTED to authorize the Executive Director's Office to purchase an electric typewriter to be paid for from

. . . in functional G.I. disorders*

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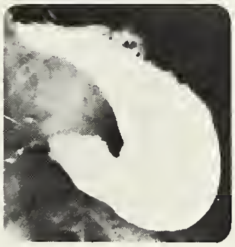

Pylorospasm has almost totally blocked passage of barium meal.

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†See Warnings, Precautions and Adverse Reactions.

See following page for prescribing information.

Reference:
King, J.C. and Starkman, N.M.: Evaluation of an antispasmodic. Double-blind evaluation to control gastrointestinal spasms occurring during radiographic examination. A preliminary report. Western Med. 5:356-358, 1964.

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INDICATIONS
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IT SHOULD BE NOTED AT THIS POINT IN TIME THAT THERE IS A LACK OF CONCURRENCE AS TO THE VALUE OF ANTICHOLINERGICS/ANTISPASMODICS IN THE TREATMENT OF GASTRIC ULCER IT HAS NOT BEEN SHOWN CONCLUSIVELY WHETHER ANTICHOLINERGIC/ANTISPASMODIC DRUGS AID IN THE HEALING OF A PEPTIC ULCER, DECREASE THE RATE OF RECURRENCES, OR PREVENT COMPLICATION

Based on a review of this drug by the National Academy of Sciences—National Research Council and/or other information, FDA has classified the following indications as "probably" effective

May also be useful in the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis, acute enterocolitis, and functional gastrointestinal disorders); and in neurogenic bowel disturbances (including the splenic flexure syndrome and neurogenic colon).

THESE FUNCTIONAL DISORDERS ARE OFTEN RELIEVED BY VARYING COMBINATIONS OF SEDATIVE, REASSURANCE, PHYSICIAN INTEREST, AMELIORATION OF ENVIRONMENTAL FACTORS

For use in the treatment of infant colic (syrup)

Final classification of the less-than-effective indications requires further investigation

CONTRAINDICATIONS Obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis), paralytic ileus, intestinal atony of the elderly or debilitated patient, unstable cardiovascular status in acute hemorrhage, severe ulcerative colitis, toxic megacolon complicating ulcerative colitis, myasthenia gravis WARNINGS In the presence of a high environmental temperature, heat prostration can occur with drug use (fever and heat stroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy In this instance treatment with this drug would be inappropriate and possibly harmful Bentyl may produce drowsiness or blurred vision In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery or perform hazardous work while taking this drug PRECAUTIONS Although studies have failed to demonstrate adverse effects of dicyclomine hydrochloride in glaucoma or in patients with prostatic hypertrophy, it should be prescribed with caution in patients known to have or suspected of having glaucoma or prostatic hypertrophy Use with caution in patients with autonomic neuropathy, hepatic or renal disease, ulcerative colitis—Large doses may suppress intestinal motility to the point of producing a paralytic ileus and the use of this drug may precipitate or aggravate the serious complication of toxic megacolon, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, and hypertension, hiatal hernia associated with reflux esophagitis since anticholinergic drugs may aggravate this condition

It should be noted that the use of anticholinergic/antispasmodic drugs in the treatment of gastric ulcer may produce a delay in gastric emptying time and may complicate such therapy (antral stasis) Do not rely on the use of the drug in the presence of complication of biliary tract disease Investigate any tachycardia before giving anticholinergic (atropine-like) drugs since they may increase the heart rate With overdosage, a curare-like action may occur ADVERSE REACTIONS Anticholinergics/antispasmodics produce certain effects which may be physiologic or toxic depending upon the individual patient's response The physician must delineate these Adverse reactions may include xerostomia, urinary hesitancy and retention, blurred vision and tachycardia, palpitations, mydriasis, cycloplegia, increased ocular tension, loss of taste, headache, nervousness, drowsiness, weakness, dizziness, insomnia, nausea, vomiting, impotence, suppression of lactation, constipation, bloated feeling, severe allergic reaction or drug idiosyncrasies including anaphylaxis, urticaria and other dermal manifestations; some degree of mental confusion and/or excitement, especially in elderly persons, and decreased sweating With the injectable form there may be a temporary sensation of lightheadedness and occasionally local irritation DOSAGE AND ADMINISTRATION Dosage must be adjusted to individual patient's needs

*Usual Dosage* Bentyl 10 mg capsule and syrup *Adults* 1 or 2 capsules or teaspoonfuls syrup three or four times daily *Children* 1 capsule or teaspoonful syrup three or four times daily *Infants* ½ teaspoonful syrup three or four times daily (May be diluted with equal volume of water ) Bentyl 20 mg *Adults* 1 tablet three or four times daily Bentyl Injection *Adults* 2 ml. (20 mg ) every four to six hours intramuscularly only NOT FOR INTRAVENOUS USE MANAGEMENT OF OVERDOSE The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot, dry skin, dizziness, dryness of the mouth, difficulty in swallowing, CNS stimulation. Treatment should consist of gastric lavage, emetics, and activated charcoal Barbiturates may be used either orally or intramuscularly for sedation but they should not be used if Bentyl with Phenobarbital has been ingested If indicated, parenteral cholinergic agents such as Urecholine® (bethanecol chloride USP) should be used

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the Russell Fund, approximate range—$400 rebuilt, $700 new.

(f) *American Association of Medical Society Executives (AAMSE):* It was VOTED to authorize the expenditure of $200 in support of the AAMSE Education Fund.

(g) *Fifth AMA State Health Legislation Meeting (Jan. 4-6, 1979):* It was VOTED to authorize James W. Tierney, M.D., Chairman of the CSMS Committee on Legislation, and Atty. John Pickett, CSMS Legislative Counsel, to attend the subject meeting at an estimated cost of $500 each.

(h) *AMA National Leadership Conference (Feb. 15-18, 1979):* It was VOTED to authorize the Vice President of the Society, W. Raymond James, M.D., and the executive director, Tim Norbeck, to attend the subject meeting in Chicago.

(i) *Request of the Cancer Coordinating Committee:* It was VOTED to grant the subject committee up to $2,000, if necessary, in support of a series of Cancer Seminars which will be held in Connecticut during 1979.

### Seminar on Canadian Health Care System

It was VOTED to disseminate Tim Norbeck's report to the two U.S. Senators and six U.S. Congressmen from Connecticut and to recommend that the Editor of Connecticut Medicine consider it for publication.

### The Cancer Coordinating Committee

David Fischer, chairman of the subject committee, and invited guest of the Council, discussed two separate requests of his committee relating to those physicians "qualified" to administer chemotherapy and endorsement of the Tumor Registrar's Association of Connecticut (TRAC). After discussion, the Council elected not to take a position on those qualified to administer chemotherapy, but VOTED to endorse TRAC as a professional association of individuals whose work constitutes a vital component of Connecticut's efforts to study and control cancer.

### Federal Trade Commission

Society legal counsel, Attorney Linda Randell of Wiggin & Dana, described at length the recent decision of the FTC administrative law judge charging the American Medical Association and the Connecticut State Medical Society with restraining physician advertising.

It was VOTED to appeal the decision utilizing CSMS counsel up through the full Federal Trade Commission and then to reappraise the situation at that time. It was further VOTED to distribute a press release to that effect.

Atty. Randell explained that a decision from the full Federal Trade Commission could be available as early as July, 1979, but it was also very possible that it might take several months longer.

### Committee on Insurance

Robert Jordan, M.D., Chairman of the Society's Committee on Insurance, apprised the Council of recent developments relative to the Society's sponsored insurance plans. He reported that the committee was requesting Council action on the Group Overhead and Life Insurance Plans. After discussion a motion was made, that in order to protect those members who already have group overhead insurance, the Society continue to support the Group Overhead Insurance program administered by the Schiff Agency and also to support the sale of overhead insurance by the Ayr Agency so that members can have a choice. The motion was tabled until further information could be obtained on the viability of the present Group Overhead Program.

### Membership on AMA Councils

The Council agreed that Drs. J. Alfred Fabro and Jerome K. Freedman should become candidates for the AMA Councils on Medical Service and Continuing Physician Education, respectively. It was determined that any other suggested nominees could be submitted by a councilor at the January 10 meeting.

NEXT MEETING: Wednesday, January 10, 1979.

CHANGE OF DATE: The scheduled Council meeting on April 4th has been changed to March 28th due to conflict with county meetings.

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on December 13, 1978. Detailed minutes of the meetings are on file at 160 Ronan Street, New Haven, for perusal by any interested member of the Society.*

### NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS.** This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

J. Alfred Fabro, M.D., Editor
*Connecticut Medicine*
160 St. Ronan Street, New Haven, Connecticut 06511

# In Memoriam

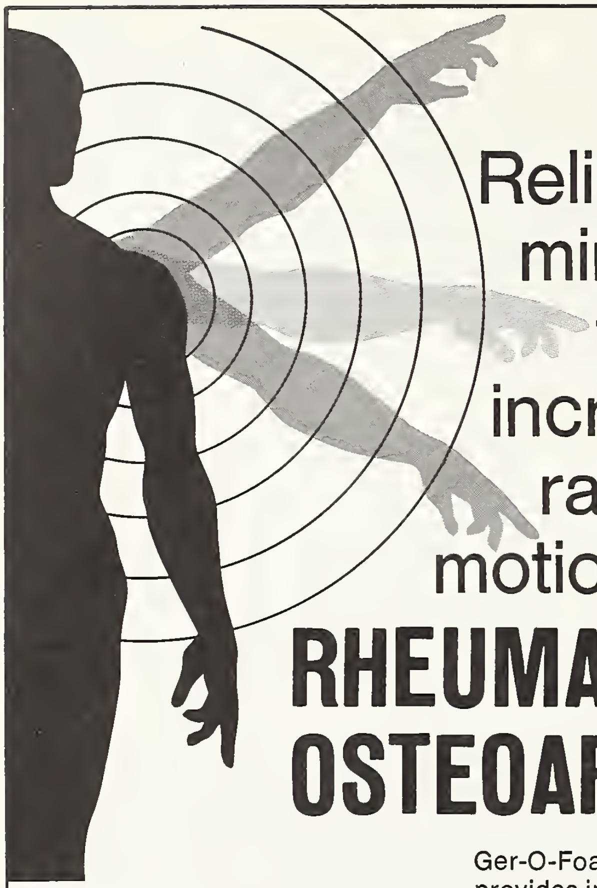
**CORRIDON, JAMES D.,** Georgetown Medical School, 1928. Dr. Corridon was a general practitioner in the Fairfield area since 1930. He served as a member of the surgical staff at Norwalk Hospital and was for many years the Norwalk Health Officer. He was also a past president of the Norwalk and the Fairfield County Medical Societies and a member of the Fairfield County Medical Society, the Connecticut State Medical Society and the American Medical Association. Dr. Corridon died October 21, 1978, at the age of 77.

**DUZMATI, PAUL P.,** Jefferson Medical College, 1936. Dr. Duzmati was a general practitioner in the Fairfield Area since 1937. He served in the U.S. Army during World War II as the European Theater Medical Corps Captain and was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Duzmati died October 14, 1978, at the age of 69.

**GURWITZ, JACK,** Tufts Medical School, 1938. Dr. Gurwitz was a practicing surgeon in the Hartford area since 1946. He was a member of the surgical department at Mount Sinai Hospital and was also a courtesy staff member at St. Francis Hospital and Medical Center and Hartford Hospital and served in the medical corps during World War II. Dr. Gurwitz was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. He died November 26, 1978, at the age of 66.

**KILGUS, JOHN F.,** University of Maryland, 1931. Dr. Kilgus, who practiced medicine in Litchfield from 1935 to 1951, was chief of health services for state employees, State Department of Health, from 1951 to 1973 when he retired. He was a past member of the staff of New Haven Hospital, Waterbury Hospital and Charlotte Hungerford Hospital. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Kilgus died November 19, 1978, at the age of 74.

**ROMANIELLO, ROCCO J.,** Columbia University of New York, 1927. Dr. Romaniello was a surgeon in the Hartford area since 1928, and was a long time member of the surgical staff of St. Francis Hospital and Medical Center. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Romaniello died October 28, 1978, at the age of 77.



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[1] Gordon, E. E. and Haas, A., Indust. Med. & Surg. 28:217, May, 1959.

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# The Management of Chronic Venous Insufficiency

STEVEN A. GOULD, M.D. AND MORRIS D. KERSTEIN, M.D.

Chronic venous insufficiency of the lower extremities is a common and distressing situation that is frustrating for both patient and physician. Edema, dermatitis, induration, pigmentation, and ulceration are the sequellae attributed to the postphlebitic syndrome, although it is common to elicit no history of deep vein thrombophlebitis. The problem has fascinated the medical profession for more than a century, and yet the picture is still not entirely clear.

Venous hypertension in the superficial and communicating or perforating veins is the basis of the disease. The normal venous drainage of the superficial tissue in the exercising leg in the erect position is towards the deep system via the perforating veins. The venous return from the legs is enhanced by calf muscle contractions, the so-called venous pump or "peripheral heart", with blood from the soleal veins being forced back to the central circulation. During diastole, blood is actually "sucked into" the deep veins from the superficial and perforating systems. Retrograde flow is prevented by competent venous valves in the deep and perforating veins. When these fail, the high pressure in the deep system, which may reach 100 mm Hg during exercise, is transmitted back to the perforating and superficial veins. This ambulatory venous hypertension is the basis of the syndrome of chronic venous insufficiency.

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The most troublesome aspect of the syndrome is undoubtedly the venous ulcer of the ankle. The association of varicose veins and leg ulcers was first noted by Hippocrates, but there was no further progress until Harvey discovered the circulation and the role played by the venous valves. During the eighteenth and early nineteenth century most emphasis was placed on the varicose veins, and the term varicose ulcer became well accepted.

Gay[1] made a significant contribution in 1867 when he observed that varicose veins were independent of ulcers, and proposed that there were lesions of the deep veins that were responsible for the skin breakdown. He described the ankle perforating veins and introduced the term venous ulcer. There was little progress from Gay until 1917 when Homans clearly distinguished between superficial varicosities and the postphlebitic or postthrombotic state with destruction of the deep venous valves and the development of the ulcers.[2] In 1942, Bauer reported the high incidence of induration and later ulceration in patients followed carefully after deep vein thrombosis.[3] After ten years 72% of patients had advanced stasis changes, and 52% actually developed ulcers. The median time interval for the appearance of the initial ulcer was two and one-half years.

After venography was introduced, it was confirmed that following thrombosis the deep veins do recanalize, but the valves are indeed destroyed.[4] As experience increased, Linton emphasized the significance of the ankle perforators, and the consequences of their incompetence.[5-7] Crockett similarly described the destruction of these perforating venous valves as the essential cause of venous ulceration,[8] with the powerful calf pump transmitting its exceedingly high pressures to the subcutaneous tissues. Cockett further described an ulcer precursor state, where a marked flare of dilated venules occurs around the medial malleolus due to the sustained local venous hypertension. The anatomy of the perforating veins in relation to the greater and lesser saphenous veins predicts the locations of the lesions in the so-called "gaiter" area, the lower half of the leg extending upwards from around the malleoli. The term Ankle Blowout Syndrome was thus introduced to the literature.

The process is initiated when the venous hypertension overcomes the osmotic pressure gradient and results in edema. The stasis phenomenon leads to decreased functional flow and impaired cellular metabolism. The supply of nutrients is diminished,

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STEVEN A. GOULD, M.D., Research Associate, Department of Surgery, Michael Reese Hospital, Chicago, IL.

MORRIS D. KERSTEIN, M.D., Chief, Peripheral Vascular Surgery, Michael Reese Hospital, Chicago, IL; Associate Professor, University of Chicago School of Medicine.

with the enhancement of anaerobic metabolism, and increased production of lactate, alanine and carbon dioxide. This compromised cellular function results in cell death tnd tissue loss.[9]

An intriguing mechanism is being investigated in England by Browse and his colleagues.[10] [11] He postulates the venous hypertension stimulates capillary proliferation in the dermis, with the development of wide intercellular pores at their venular end that may promote increased capillary permeability to large molecules such as fibrinogen. He has observed increased fibrin deposition around the capillaries, and diminished fibrinolytic activity. Whether this is a primary defect or secondary phenomenon is not known. This cuff of fibrin might well form a barrier to the diffusion of oxygen and nutrients, and lead to cell death. In addition, such a diffusion barrier to the tissues could explain the puzzling high oxygen content observed in the venous blood of the postphlebitic leg.[12]

Even more exciting is the successful experience Browse has described using oral androgenic steroids to reverse some of the skin changes.[11] Since these agents enhance fibrinolysis, they theoretically reverse the skin induration by decreasing fibrin deposits and improving fibrinolytic activity. Although it is only a limited experience, the results have been most encouraging.

Once the importance of the incompetent perforators was established, it became apparent that their destruction could result from primary pathology, or secondary to the high pressure of deep vein or saphenous incompetence. It is generally accepted that the postphlebitic state is the most common etiology. The underlying cause is significant, since the treatment will vary. The correct diagnosis may be made by clinical examination, venography, and venous pressure measurements. While the results would seem to be apparent in the first two, they may not be as accurate as the direct measurements. Table I demonstrates the distinction between varicose and postphlebitic ulcers.[13] Furthermore, if the abnormal pressures are due only to saphenous incompetence, a tourniquet on the thigh will restore a normal exercise pressure. Obviously this will not alter the response with abnormal perforators. Several elegant pressure and flow studies have been reported by Bjordal,[14-16] and such information is particularly helpful in selecting the appropriate therapy for each patient.

Table I

VENOUS PRESSURE MEASUREMENTS

| *Condition* | *Standing* | *Exercise* | *Time to Return To Standing* |
|---|---|---|---|
| Normal Veins | 90 mm Hg | 0-30 mm Hg | 31 seconds |
| Primary Varicose Veins | 90 mm Hg | 45-60 mm Hg | 3 seconds |
| Postphlebitic State | 90 mm Hg | 75-90 mm Hg | Immediately |

An understanding of this abnormal physiology leads to a logical plan of treatment. The main goal of therapy is the reduction of the local venous hypertension. If the cause is primary saphenous insufficiency, proper surgery will be curative. The postphlebitic state, however, is a chronic disease without any permanent cure. The therapeutic options are elevation, compression and surgery. The first step is patient education, often done best in a vascular clinic with a team that includes a surgeon, an internist, and a nurse clinician serving as a coordinator to ensure continuity of care. All complicating medical problems—congestive heart failure, anemia, obesity, diabetes— must be managed aggressively.

Elimination of infection and maximal healing of the ulcer is essential. The myriad of topical agents employed should testify to their futility. Significant cellulitis should be treated with systemic antibiotics, but otherwise there is no advantage to any pharmacologic manipulation. Wet-to-dry saline compresses every four to six hours is an effective cleansing and debriding method, and quite inexpensive.

Although it is impractical to keep a patient at bedrest indefinitely, this would truly prevent progression of new ulcerations, since elevation of the extremities above the level of the heart would provide constant reduction of the venous hypertension. For ulcers particularly refractory to ambulatory management, however, periods of bedrest and sustained elevation can be quite effective.

An alternative to sustained elevation is adequate compression, which can be accomplished in a variety of ways. Elastic heavy support hose, pulsating boots, and elastic bandage over a sponge rubber pad are all satisfactory. In properly selected patients, Unna boots may be applied for monthly periods with excellent results. Education about the sensation of fullness, fatigue, or edema in the extremity is mandatory, so proper elevation can be accomplished promptly by the patient before more damage occurs. This is also of prime importance for prophylaxis in any patient treated for deep vein thrombosis.

Careful ambulatory management has been successful in 85% of the cases of the postphlebitic syndrome in Owens' experience.[17] When such conservative measures are still inadequate after three to six months, however, surgical intervention may be indicated. As noted above, the main goal when contemplating surgery should be the prevention of further ulceration, and the etiology of the venous hypertension must be identified. In addition to the saphenous and deep calf vein abnormalities, Cockett has identified a major proximal venous obstruction due to segmental iliofemoral thrombosis.[13] Dale has popularized the crosspelvic vein graft with good results, but there are few other reported series.[18] The majority of patients requiring surgery are in the other two categories.

Cranley has found 25% of venous ulcers due to superficial venous incompetence, and the remainder secondary to disease of the deep system,[19] figures confirmed in other series. The superficial situation is a curable condition, and is handled by the standard removal of the saphenous system and ligation of perforators. There is no residual swelling, no long term need for compression, and the recurrence rate is about 4%.

Intervention for the true postphlebitic syndrome, however, is only one aspect of the treatment of a chronic disease. The surgical options include: (1) varicose vein removal and ligation of the perforators, (2) deep vein ligation, (3) reconstruction of the deep venous pump, and (4) sympathectomy.

Needless to say, sympathectomy no longer plays a role in the treatment of venous ulcers. Restoration of the deep venous pump has been attempted by femoropopliteal reconstruction by Husni,[20] and transvenous repair of the femoral vein valve by Kistner,[21] but the experience is limited and not without certain questions.

The only real option remains the Linton procedure,[7] or one of its modifications.[22] The original description described the radical removal of the superficial system, ligation and division of all perforating veins, ligation and division of the superficial femoral vein, and removal of a portion of the deep fascia of the lower leg. Few surgeons today ligate the femoral vein, despite Linton's large experience and reported low morbidity. The general approach includes ligation and stripping of the saphenous system, and ligation of the perforators in either an extrafascial or subfascial approach.

Obviously the ulcer must be in the best state possible prior to any surgery. If still unhealed, excision followed by split thickness skin grafting, either immediately or delayed, must be performed. A wide dissection is not as important as the depth, so all fibrosed scar tissue is removed.

Preoperative marking of all veins is essential. Meticulous attention must be paid to hemostasis intraoperatively. The posteromedial incision carried through skin, fat, and fascia is used most often, but either the extrafascial approach, or a variety of other incisions may be substituted. The preoperative examination, venogram, and pressures if obtained are helpful in locating all areas of pathology. Compression bandages and elevation are important postoperatively, although limited ambulation is encouraged. Education must still be emphasized following surgery, with the same attention given to the symptoms of edema and fatigue to ensure proper elevation and compression, and thus prevention of new difficulties.

The results are time dependent. While initially quite satisfactory, Cranley reports that the recurrence rate approaches 33% after fifteen years.[19] It must therefore be carefully explained to each patient that the postphlebitic state is a life-long disease, unlike primary saphenous incompetence.

Several recent reports by Burnand have further emphasized the differences in the two etiologies of venous ulcers. In the first series,[23] forty-one patients with ulceration had surgery as described above and were followed for five years. In all twenty-three cases of deep vein damage there was recurrent ulceration, while only one of the eighteen patients with a normal deep system had a recurrence. The second report[24] was a careful evaluation of venous pressures pre- and postoperatively, and provided data to both support and predict such poor results based on a persistent deep vein abnormality. This was the first careful physiologic study of the results of surgical therapy.

There is thus no ideal solution to this difficult problem at present. Successful therapy for the true postphlebitic syndrome will depend on better means of prevention, and the development of a method for restoring the normal pressure flow characteristics of the calf muscle pump.

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# Intussusception Causing Intestinal Obstruction in Pregnancy

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**ABSTRACT—Intussusception occurring during pregnancy is an extremely infrequent event. Due to its rarity and the fact that symptoms of intestinal obstruction mimic closely complaints of nausea, vomiting, and abdominal pain commonly encountered in obstetrical practice, the diagnosis is likely to be delayed with serious sequellae for both mother and child. This paper reviews the pertinent literature and adds two cases which illustrate the diagnostic and therapeutic challenge posed by this unusual complication of pregnancy.**

### Introduction

Intestinal obstruction is an infrequent complication of pregnancy and is rarely due to intussusception. A review of the literature from 1914 through 1975 uncovered only 13 reported examples of intussusception complicating pregnancy.[1-8] Two additional cases were encountered in the 34,032 pregnancies delivered at Saint Francis Hospital and Medical Center from 1967 to 1977. Since definitive diagnosis and therapy was delayed in both these individuals, it seemed appropriate to add their case reports to the literature and re-emphasize the clinical features of this syndrome.

### Case Reports

**Case No. 1 - A.S.**

This 28-year-old white gravida 4, para 3, was admitted to Saint Francis Hospital and Medical Center at 24 weeks of gestation complaining of nausea, vomiting, and right upper quadrant pain of 2 days duration. Her past medical history and review of systems were unremarkable. Her temperature, pulse, respirations, and blood pressure were within normal limits. Involuntary guarding and tenderness were noted in the right upper quadrant but rebound tenderness was absent. Bowel sounds were diminished. The uterus was appropriately enlarged for a gestation of 24 weeks and was not tender. Fetal heart tones were clearly audible at a rate of 140 per minute. Rectal examination was negative. The hematocrit was 34% and the white blood cell count 10,000 per cu. mm. with a normal differential. Serum amylase and liver function studies were reported as normal. Urinalysis revealed 3+ ketones but was otherwise unremarkable. The admitting diagnosis was acute cholecystitis.

Initially, the patient was allowed nothing by mouth and was maintained on intravenous fluids. Small doses of parenteral analgesics were administered. On the first hospital day, a low-grade fever developed, and chloramphenicol, 1 gram intravenously every

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8 hours, was instituted. Despite these measures, the patient failed to improve and temperature elevations to 102° F. and 103° F. were observed on the second and third hospital days.

On the fourth hospital day, the patient became acutely ill with a fever of 105° F., chills, and increasing right upper quadrant pain. The laboratory reported a white blood cell count of 6,200 with 93% polymorphonuclear neutrophils. Emergency laparotomy was performed but, despite careful exploration, no significant gross pathology was found. A catheter cholecystostomy was carried out in view of the strong clinical impression of biliary tract disease. A biopsy of the gallbladder obtained at the time of the procedure revealed chronic cholecystitis. Cultures of the gallbladder and common bile duct contents were sterile.

Postoperatively, the patient continued to complain of upper abdominal pain although her laboratory data, including white blood cell count, serum amylase, and serum diastase, remained within normal limits. On the first postoperative day, premature labor developed and the patient delivered a 1000 gram female fetus who died after 12 hours of life.

The immediate post-partum period was complicated by an apparent adynamic ileus with intermittent vomiting and episodes of abdominal pain. Repeated x-ray studies confirmed the clinical impression. This situation recurred intermittently despite appropriate intravenous replacement therapy, nasogastric suction, and the passage of a cantor tube. On the 12th postoperative day, her abdominal pain became more severe, and her temperature rose to 101° F. Examination revealed a distended tender abdomen with high pitched and hyperactive bowel sounds. The white blood cell count was 8,200 per cu. mm. with a normal differential. Abdominal radiographs at this time were consistent with small bowel obstruction.

The patient was brought once again to the operating room for a second exploratory laparotomy. An ileo-ileocolic intussusception was found with gangrene of a small bowel segment approximately 15 centimeters in length. Small bowel resection with end to end anastomosis was performed. Recovery from surgery was prolonged but essentially uneventful and the patient was discharged on the 34th hospital day.

**Case No. 2 - B.R.**

This 25-year-old black gravida 2, para 1, was transferred from another hospital to our institution at 20 weeks of gestation for evaluation of recurrent episodes of abdominal pain, nausea, and vomiting of 3 months duration. The patient had been hospitalized on numerous occasions during the preceding two years for similar complaints which were never satisfactorily explained. Her past history and review of systems were otherwise unremarkable. Physical examination revealed a clinically dehydrated woman whose temperature was 101.4° F. Her blood pressure was 130/80 mm.Hg, pulse rate 120 per minute, and respirations 18 per minute. Mild tenderness and voluntary guarding were noted over the upper abdomen. Bowel sounds were diminished in frequency and several examiners remarked upon an ill-defined, soft, epigastric mass. The uterus was appropriately enlarged for gestational age and fetal heart tones were audible. Laboratory data included a hematocrit of 35% and white blood cell count of 9,000 per cu. mm. with a normal differential. Serum electrolytes were normal. The urinalysis revealed 3+ ketones. Ultrasonography was ordered because of the questionable upper abdominal mass and revealed what appeared to be a dilated loop of bowel draped across the superior surface of the uterine fundus.

Appropriate intravenous fluid replacement therapy was ordered and, because of persistent vomiting, nasogastric suction was instituted. A consulting gastroenterologist entertained the diagnosis of penetrating peptic ulcer with pancreatitis. On the 3rd hospital day, endoscopy revealed only diffuse gastritis. Antacid therapy produced little relief of symptoms. The following day, bright red rectal bleeding was noted and the hematocrit fell to 25%. The patient's prothrombin time, initially 12 seconds (control, 14 seconds) was reported as 29 seconds (control, 13 seconds). Parenteral vitamin K and oral iron were ordered. Sigmoidoscopy and rectal biopsy were normal. A barium enema revealed no abnormality of the colon or the segment of terminal ileum visualized on the films. Serum amylase concentrations reported on the 4th and 8th hospital days were elevated at 210 units per 100 ml. and 152 units per 100 ml. respectively (normal under 160 units per 100 ml.) and urinary diastases were greater than 600 units per hour (normal less than 300 units per hour).

Bright red rectal bleeding continued through the 10th hospital day when the patient's hematocrit was measured at 19.8%. The patient refused transfusion because of her religious beliefs. The following day, a left upper quadrant abdominal mass became clearly palpable. Repeat ultrasonography revealed an ellipsoidal cyctic mass, superior to the uterus, felt to represent a pancreatic pseudocyst.

Because of the patient's protracted course, a subclavian catheter was inserted on the 11th hospital day and hyperalimentation therapy instituted. This was continued over the next three weeks during which period the nausea, vomiting and abdominal pain resolved and the rectal bleeding ceased. The patient's hematocrit stabilized in the range of 25%. Serial ultrasonography demonstrated a steady decrease in the size of the upper abdominal cystic mass and its ultimate disappearance.

By the 32nd hospital day, after three weeks of continuous nasogastric suction and hyperalimentation, oral feedings were begun and gradually progressed to a regular diet. Her weight which had remained steady during the period of hyperalimentation, increased. During her hospital stay, enlarging uterine size and serial biparietal diameter measurements suggested normal fetal growth. The patient was discharged, asymptomatic, and in apparently good condition on the 46th hospital day.

After a six-week interval during which the patient was free of unusual symptoms, she suddenly developed a recurrence of upper abdominal pain, nausea, and vomiting which prompted her readmission. Moderate epigastric tenderness and voluntary guarding were again noted. Bowel sounds were absent. The uterus was appropriately enlarged to the size of a 33-week gestation and no other abdominal masses were identified. Her temperature was normal, white blood cell count was 5,300 with a normal differential, hematocrit was 29.1% and serum amylase was normal. Flat and upright films of the abdomen revealed a normal gas pattern and an intrauterine pregnancy consistent with her dates. The impression of the admitting physician was recurrent pancreatitis. Nasogastric suction, intravenous fluid replacement therapy and appropriate analgesics were continued over the ensuing two weeks with only intermittent relief of the patient's symptoms. Amniocentesis on the 2nd hospital day revealed an L/S ratio of 1.4. Her temperature, serum amylase, and liver function studies, urinary diastase determinations and white blood cell counts remained normal. Several abdominal films were obtained but were not diagnostic. Eventually, a steady increase in the severity of the patient's abdominal pain suggested the advisability of exploratory laparotomy. At 35 weeks of gestation, the abdomen was entered and a 2,300 gram infant male in good condition was delivered by low segment transverse cesarean section. The abdomen was thoroughly explored by the obstetrician and a consulting general surgeon neither of whom was able to discover any palpable or visible pathology.

The patient felt remarkably improved during her first three postoperative days but then began to experience intermittent episodes of progressively severe upper abdominal pain. On the seventh postoperative day (the 21st hospital day), she became acutely ill with a temperature of 102° F., generalized abdominal distention, tenderness, and rebound tenderness. Her white blood cell count which had been normal was reported as 12,000 per cu. mm. with 5% neutrophils and 83% band forms. Grossly purulent material was obtained by paracentesis. An emergency laparotomy was performed and a jejuno-jejunal intussusception was discovered with gangrenous perforation of the involved small bowel segment. A small bowel resection with end to end anastomosis was performed. The patient's postoperative course was complicated by pneumonia which responded to appropriate antibiotic therapy and she was discharged on the 39th hospital day in good condition.

## Discussion

Intestinal obstruction is an uncommon complication of pregnancy although one which seems to be reported with increasing frequency. A review of the available literature (Table 1) indicates incidence estimates ranging from 1 in 66,431 deliveries to 1 in 2,652 deliveries. Adhesive bands secondary to prior abdominal surgery account for the majority of the cases suggesting that the frequency of this complication will continue to rise as an increasing number of women undergo abdominal surgery prior to childbearing.[9] [10] Adhesions classically precipitate obstruction between 16 and 20 weeks as the uterus becomes an abdominal organ; after the 36th week, as the fetal head descends into the pelvis; and during the immediate puerperium when the sudden change in uterine size alters the relationships of the intraabdominal structures.[11-13]

Table I

REPORTED CASES OF INTUSSUSCEPTION AS A CAUSE OF INTESTINAL OBSTRUCTION COMPLICATING PREGNANCY

| *Authors* | *Date* | *Number of Cases* |
|---|---|---|
| Ludwig[1] | 1913 | 4 |
| Von Mikulicz-Radecki[2] | 1926 | 3 |
| Chaffin et al.[3] | 1937 | 1 |
| Baker et al.[3] | 1953 | 1 |
| Svesko and Pisani[5] | 1960 | 1 |
| Morris[6] | 1965 | 1 |
| Moore[7] | 1967 | 1 |
| Aston[8] | 1975 | 1 |
| Total Reported Cases | | 13 |

With adhesive bands accounting for some 60 percent of intestinal obstructions seen in pregnancy,[9] [10] volvulus and intussusception follow as the second and third etiological considerations. Intussusception has been felt by some authors to account for between 4 and 6 percent of intestinal obstructions encountered in pregnant women.[11–14] In spite of this, only 13 reported examples of this complication were encountered in the literature summarized in Table 1.

Although intussusception is responsible for approximately 80 to 90 percent of intestinal obstruction in a pediatric population, it is a relatively rare (approximately 5 percent) cause of mechanical obstruction in the adult.[8] In contrast to the usually idiopathic etiology of this event in children, intussusception in the adult is generally associated with organic lesions including benign or malignant neoplasms, Meckel's diverticuli, and granulomatous lesions of the appendix. Thus, when intussusception is discovered, a careful search for associated pathology should be carried out.

Table II

REPORTED INCIDENCE OF INTESTINAL OBSTRUCTION COMPLICATING PREGNANCY

| *Authors* | *Date* | *Incidence* |
|---|---|---|
| Bemis[15] | 1932 | 2: 15,000 |
| Smith and Bartlett[16] | 1940 | 1: 66,431 |
| Matthews and Mitchell[17] | 1948 | 1: 12,000 |
| Bellingham et al.[18] | 1949 | 1: 2,652 |
| Svesko and Pisani[5] | 1960 | 1: 6,600 |
| Harer Jr.[9] | 1962 | 1: 3,587 |
| Morris[6] | 1965 | 1: 13,687 before 1950<br>1: 3,163 after 1950 |
| Goldthorp[14] | 1966 | 1: 4,990 |

In both of the patients reported here, there was marked delay in arriving at the correct diagnosis. Premature labor and subsequent neonatal death occurred in the first patient and severe maternal morbidity in both. Notably, in each of the patients, initial exploratory laparotomy was unrewarding.

The diagnosis of intestinal obstruction during pregnancy is frequently confounded by the common occurrence in normal gravidas of nausea, vomiting, and abdominal pain. The physiological leukocytosis of pregnancy may further obscure the clinical picture. Current hesitancy to order abdominal radiographs during pregnancy may deprive the obstetrician of critical information. Once the diagnosis is made, the management of intestinal obstruction in pregnant and nonpregnant patients is identical. Nasogastric or long tube intubation should be promptly instituted and fluid and electrolyte replacement ordered. Fever, increasing leukocytosis, or worsening abdominal signs as well as failure to respond to conservative methods of treatment indicate the need for immediate surgical intervention. The uterus in the first half of gestation seldom interferes with the technical approach to the bowel; in later pregnancy, cesarean section is usually necessary to permit suitable exposure. Overwhelming infection and irreversible shock are not infrequently encountered and the current maternal mortality rate of approximately 10 percent in all types of obstruction is a formidable reminder of the seriousness of this condition in pregnancy.[6] [14]

Intussusception in pregnancy presents an unusual challenge to the diagnostic acumen of the obstetrician. The obstruction may be intermittent, the symptomatology confusing, abnormal gas patterns on x-ray may not be seen, and even exploratory laparatomy may on occasion be unrewarding. The upper abdominal mass delineated by ultrasonography in our second patient should have provided an early clue to the correct diagnosis but was misinterpreted as a pancreatic pseudocyst.

## Conclusion

Intussusception causing intestinal obstruction in pregnancy is a rare event. Two additional cases have been presented which emphasize the difficulties encountered in diagnosis and the serious maternal and fetal hazards which result from delay in definitive treatment. Intermittent and atypical symptoms and signs of intestinal obstruction should suggest this diagnostic possibility to the obstetrician. The unique phenomenon of the unrewarding exploratory laparotomy would seem to deserve particular mention.

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# Bone Disease in Waldenstrom's Macroglobulinemia: A Possible Indication for Myeloma-Type Therapy

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**ABSTRACT—A 77-year-old-male with Waldenstrom's macroglobulinemia (WM) for 17 years developed multiple bone lesions. The bone lesions and the patient's bone marrow showed an infiltration with predominantly plasma cells. Radiation therapy resolved the pain of vertebral compression fractures and cyclical melphalan and prednisone therapy stabilized the patient's hematologic status and bone disease. Myeloma-type therapy may be indicated for WM patients with bone lesions and/or a predominantly plasmacytic marrow infiltration.**

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Bone disease has been considered an unusual occurrence in Waldenstrom's macroglobulinemia (WM).[1-3] This report describes a patient with WM for 17 years who developed multiple bone lesions consisting of an infiltration of predominantly plasma cells. Myeloma-type therapy stabilized the patient's hematologic status and bone disease.

## Case Report

In February 1961, a 60-year-old-male was diagnosed as having WM. His hemoglobin was 8.7 g/dl, white blood cell count (WBC) 6700/cu mm and serum viscosity 6.0 (normal 1.4-1.8). A serum protein electrophoresis revealed an "M" spike of 6.7 g/dl. A serum immunoelectrophoresis demonstrated an IgM kappa monoclonal protein.* A concentrated urine specimen was negative for Bence Jones protein. A bone marrow aspirate and biopsy revealed a marked infiltration of lymphocytes, plasmacytoid lymphocytes and plasma cells. A skeletal x-ray survey was normal.

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*Performed at the National Institutes of Health by John L. Fahey, M.D. and Alan Solomon, M.D.

In June 1961 he developed Raynaud's syndrome. Physical exam revealed retinal vein engorgement, retinal hemorrhages and hepatosplenomegaly. The viscosity was 8.0. Chlorambucil therapy and twice-a-week plasmaphereses were started. This therapy was utilized from 1961-1967 and continuously after 1970 to maintain a serum viscosity of 2.5-3.5.

In April 1977 the patient experienced midback pain and x-rays revealed a mild compression fracture of the 11th thoracic vertebra. In June 1977 he acutely developed right chest wall pain and right anterior sixth rib tenderness and x-rays showed a pathologic fracture of that rib. Both episodes of bone pain disappeared with symptomatic treatment.

The patient was admitted in November 1977 with two weeks of incapacitating mid-back pain and left anterior chest wall discomfort. Physical exam revealed restricted thoracolumbar spine motion and tenderness of the lower thoracic spine and left anterior ribs 3-5.

The viscosity was 3.5 and IgM 3420/mg/dl. A serum immunoelectrophoresis now revealed free kappa Bence Jones proteins (Figure 1). The alkaline phosphatase was 110 IU/L (normal 20-80) and the calcium and phosphorus were normal. X-rays revealed moderate compression fractures of T11, L1, and L2; diffuse osteopenia; and resolution of the prior right sixth rib fracture; but no lytic lesions. A technetium-labeled bone scan showed an increased uptake in the T11-L1 vertebral area and in three left anterior ribs (Figure 2). An open biopsy of the left anterior third rib revealed an infiltration of predominantly plasma cells with occasional lymphocytes and plasmacytoid lymphocytes (Figure 3). A posterior iliac crest bone marrow aspirate and biopsy showed a similar infiltration. Bone marrow aspirate leukocyte cultures[4] failed to demonstrate bone resorbing activity.

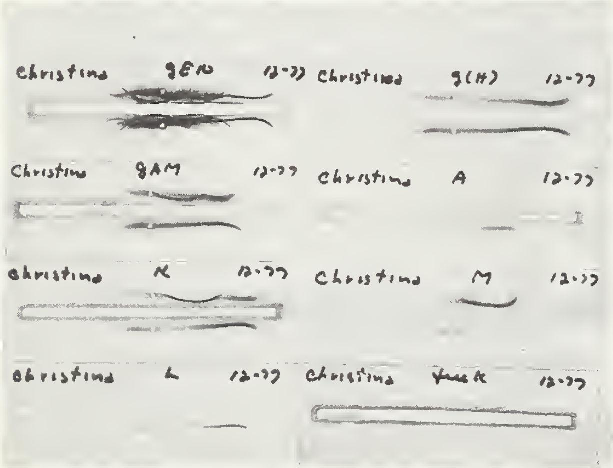

Figure 1
Serum immunoelectrophoresis showing an IgM kappa monoclonal protein and free kappa light chains.

Radiation therapy of 2000r was delivered to the low thoracic and upper lumbar areas. After two days of radiotherapy the back pain was markedly reduced and after four days the patient was fully ambulatory. Because of the predominantly plasmacytic nature of the patient's disease, therapy was started with melphalan 12 mg. and prednisone 80 mg. for four days each month.[5]

Subsequently, the patient received eight cycles of chemotherapy and required only weekly plasmapheresis to maintain a viscosity of 2.5-3.5. The rib pain resolved after the third cycle of therapy. The back pain recurred intermittently in association with physical activity but was only of a mild degree. In September 1978 the IgM was 3700 mgm/dl and viscosity 3.4. Free Bence Jones protein was no longer present in the serum immunoelectrophoresis. A bone scan showed resolution of the previous areas of increased uptake.

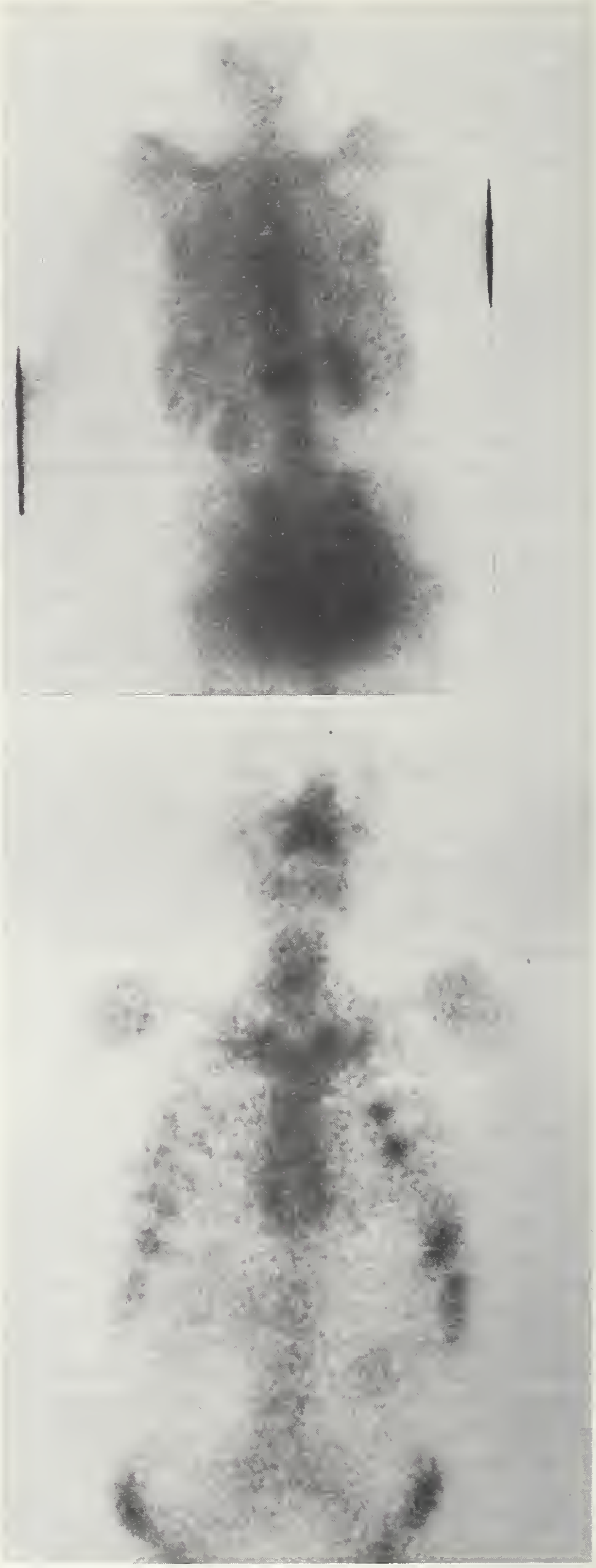

Figure 2
Technetium-labeled bone scan showing areas of increased uptake in A.) the T11-L1 vertebral areas and B.) three left anterior ribs.

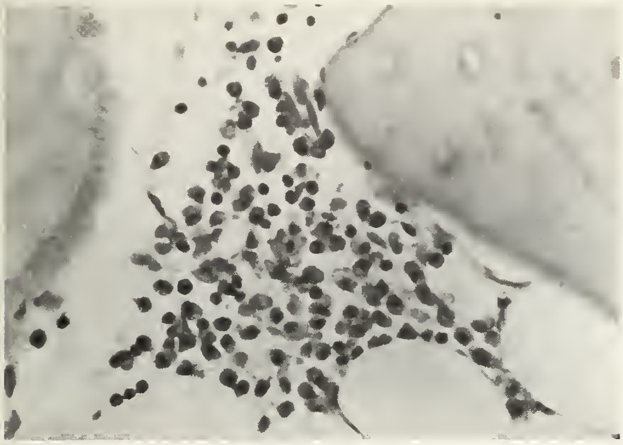

Figure 3
Left anterior third rib bone biopsy specimen showing an infiltration with predominantly plasma cells and occasional lymphocytes and plasmacytoid lymphocytes; hematoxylin-eosin, x 500.

## Discussion

Bone lesions including a pathologic rib fracture, vertebral compression fractures and diffuse osteopenia occurring in this patient were all probably due to underlying WM as supported by the rib biopsy and the response to radiotherapy and myeloma-type chemotherapy. Technetium-labeled bone scans usually do not demonstrate myeloma bone lesions because these lesions are purely osteolytic and the isotope only accumulates in areas of new bone formation. Therefore, the rib and vertebral lesions seen on bone scan in this case probably represented new bone formation in areas of pathologic fractures due to underlying WM.

Bone disease has been considered a rare occurrence in WM[1-3] with a suggested incidence of 2%.[3] Although 20 cases of bone disease complicating WM were reported in the European literature between 1950-1960,[1 6] many did not substantiate the diagnosis with immunoelectrophoresis and "macroglobulins" demonstrated on ultracentrifugation in these cases may have been polymers or aggregates of IgG or IgA.[2 7] Only 36 cases of immunoelectrophoretically-confirmed WM have been complicated by bone lesions including single or multiple osteolytic lesions, generalized osteopenia, vertebral compression fractures, and pathologic bone fractures.[2 3 6-15] A bone scan performed in a single patient was normal.[9]

Pathologic examination of osteolytic lesions and collapsed vertebrae was performed in 4 of the 36 cases[4 7 8] and revealed a diffuse infiltration of plasma cells. A similar plasmacytic infiltration was found in 10 of 19 bone marrows examined.[2 3 7-12] This finding of predominantly plasma cells in the bone marrow of a patient with WM, especially after months to years of chemotherapy, should alert physicians to the possible eventual development of bone lesions.[7 9]

Radiation therapy has been reported previously to relieve the pain of localized WM bone lesions.[7-9] In addition, two prior cases of WM with multiple osteolytic lesions and a predominant plasma cell infiltration of the bone marrow responded to melphalan and prednisone therapy with a decrease in plasma cells, an improved hematologic status and a stabilization of the bone lesions.[3 9] Our patient showed a similar improvement in his bone disease and a stabilization of his hematologic status. Moreover, his serum Bence Jones protein disappeared and his plasmapheresis requirement decreased to maintain stable IgM and viscosity levels. Myeloma-type chemotherapy may be indicated for WM patients with predominantly plasma cells in the bone marrow and/or with bone disease.

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# Intraocular Lens Implantation

JOHN B. FRANKLIN, M.D., F.A.C.S.

## Introduction

1977 marked the twenty-fifth anniversary of intraocular lens implantation. The procedure was first performed in England in 1952 by Ridley, but was probably conceived of by the rogue ophthalmologist Tandini in the 18th century. The history of active lens implantation in this country extends to 1969, although the operation was performed here as early as 1953.

Last year, more than 10,000 lens implantations were performed in this country. There are approximately 1,000 American Ophthalmologists currently performing the procedure. Despite such a long experience in lens implantation, the Food and Drug Administration has declared the intraocular lens a new device, and has launched the most intensive clinical study ever undertaken in the history of that bureau to determine the efficacy of lens implantation.

Due to the extensive coverage of this operation in the lay press, many patients are requesting further information from their physician regarding this procedure. It is the purpose of this paper to provide the non-ophthalmologist with that information.

## Historical Background

During World War II, a number of aviators were observed to have intraocular plexiglass in their eye as a result of bullet holes to the aircraft canopy. The plastic (poly methyl methacrylate-PMMA) was noted to be well tolerated within the eye, provoking no foreign body reaction. Ridley, Strampelli, Barraquer, and others designed plexiglass lens implants in the fifties. Some of these lenses were held in place by the pupil, while others were placed across the width of the anterior chamber. Despite initial visual success, most of these initial attempts eventually failed, mainly due to dislocations of the implant with subsequent corneal edema.

The dedicated work of Binkhorst and Worst in Holland during the late fifties and early sixties, eventually convinced the ophthalmologic world that lens implantation was indeed a practical, and sometimes desirable alternative to spectacle or contact lens correction of aphakia.

## Why the Intraocular Lens?

With uncomplicated, successful cataract surgery, most binocular aphakes can be fitted with spectacles. Since the aphakic eye is usually markedly hyperopic, the thick, highly convex lenses are subject to a number of problems which lead to patient dissatisfaction. First, due to thickness, the lenses are magnifying in nature, and must constantly be fitted at a precise distance from the eye so as to not alter magnification. Therefore, they go out of adjustment easily. Next, the edge thickness creates peripheral aberration and constriction of peripheral field, although with aspherically ground lenses and patient encouragement, these problems are usually overcome by the average individual. Lastly, the lens thickness and bulk renders them unsightly to many patients.

The presence of monocular aphakia poses a more complex problem. If an aphakic spectacle lens were placed in front of one eye combined with the ordinary correction in front of the non-operated eye. the resultant difference in magnification for the two eyes results in different image sizes (anisometropia). An aphakic spectacle lens produces an image size magnification of about 25% which cannot be overcome by most patients.

The use of an aphakic contact lens reduces this image size differential to about 3-8% which will allow fusion of the two images. In addition, the contact lens relieves the loss of peripheral vision objected to by many aphakic spectacle wearers. Approximately 25% of aphakes are unsuitable contact lens candidates or reject the use of the contact lens. Patients may be

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unsuitable due to poor motivation, arthritis of the hands, Parkinsons Disease, or other conditions which may interfere with the insertion and removal of the contact lens. Contact lenses which may be continuously worn, without need for daily removal are presently in a developmental stage and will probably be available in the not too distant future.

The implantation of an optical system within the eye further reduces the image size differential to about 1%, and causes no changes in peripheral vision. Therefore, the intraocular lens implant may be the procedure of choice for the monocular cataract patient who is not a contact lens candidate.

## Indications

The limited experience in this country with the intraocular lens in terms of years of follow up, has led most conservative ophthalmic surgeons to use the age of 60 as the current lower age limit for the procedure. The reasoning being that if problems begin to become evident 15 or 20 years post operatively, actuarially most patients will be dead.

There are however, some accepted indications for lens implant surgery under the age of 60, especially monocular cataracts in patients who work in a dusty environment, or other reasons precluding the use of a contact lens. Although lens implants are done only occasionally in children, they may have a valid indication in the mentally retarded cataract patient.

Secondary lens implantation, that is a lens implant performed at some time after the original cataract surgery, is performed by a few surgeons in this country and in England. Early results seem to show that this is a feasible procedure, although precise indications must be firmly established.

## Technique

There are currently 10 to 15 types of lens implants available. Some of these are pictured in Figure I. The lenses are fabricated of PMMA, at times with additional supporting structures of polypropylene and/or platinum-iridium.

Some lenses are designed for use after intracapsular extraction, the procedure in which the entire crystalline is removed. These lenses are often clipped into place on the iris by polypropylene loops, or supported from the iridectomy by a platinum clip (Figure II).

Today, there is a growing interest in the revival of the extracapsular cataract extraction. In this procedure, the posterior lens capsule is left behind, while the remainder of the lens content (nucleus, cortex) is removed from the eye. The phacoemulsification procedure (Kelman, ultrasound) is an extracapsular operation. There are additional lens styles which may be used after the extracapsular operation. These are termed capsule supported lenses.

Choyce has developed a lens implant which is supported by the width of the anterior chamber (Figure III). This lens is easier to insert than others, and has gained wide use. Manufacturing difficulties have given the Choyce lens a bad reputation among some ophthalmic surgeons, due to uveitis, glaucoma and hyphema—necessitating lens removal.

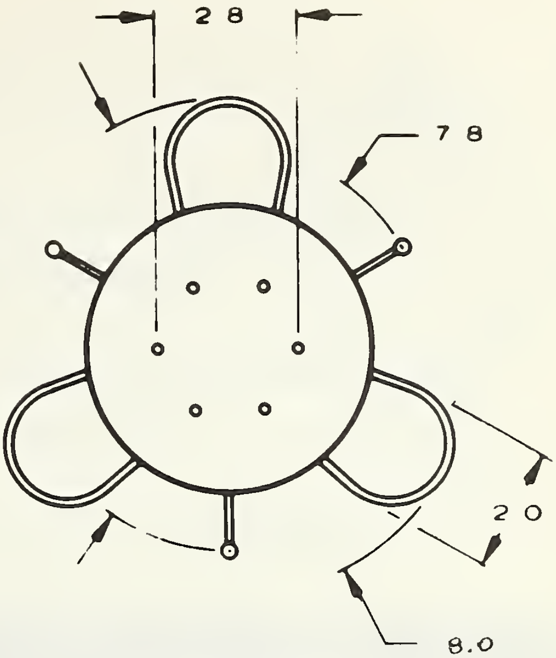

Figure IA
The Fedorov (Sputnik) Lens

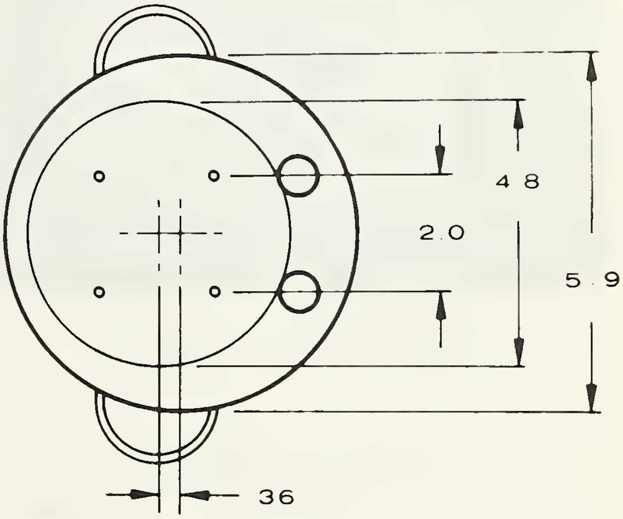

Figure IB
The Suture Medallion

The lens insertion, like the remainder of the cataract operation should be performed under the operating microscope, and most often adds but a few minutes to the operating time.

Post operatively, the successful, uncomplicated patient notes an immediate visual result, often at the first dressing change. Spectacle over-correction is usually necessary, but is not of the thick aphakic type.

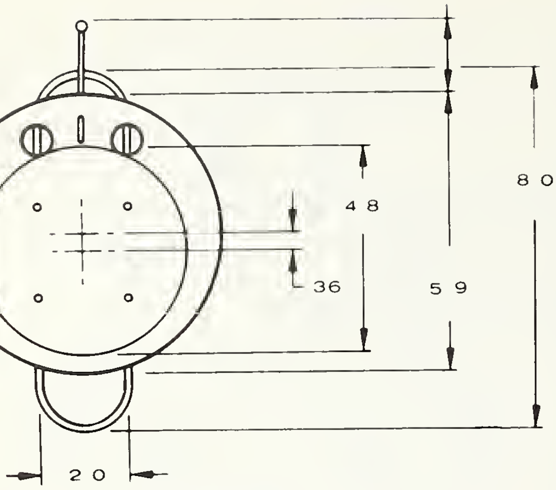

Figure IC
The Platinum Clip Lens

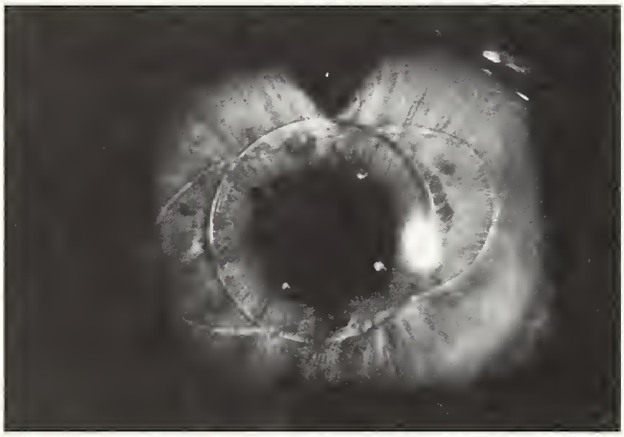

Figure II
A Pupillary Supported Lens Implant

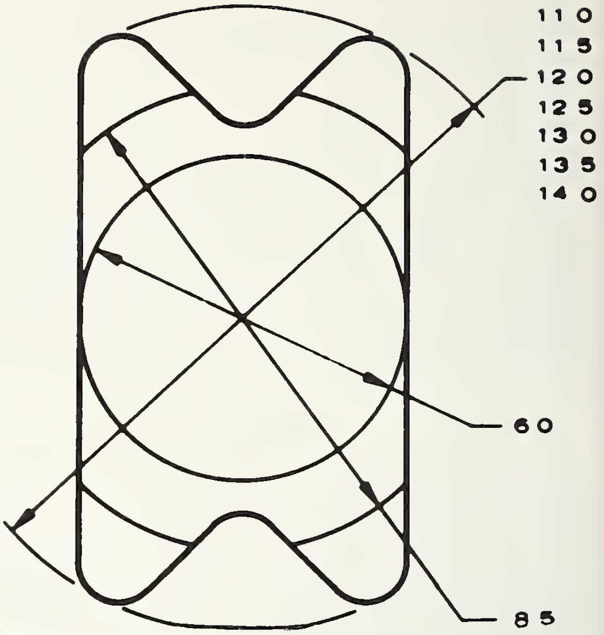

Figure III
The Choyce Anterior Chamber Lens

## Results and Complications

A recent survey comparing the results of standard cataract surgery with those after lens implantation revealed that approximately 84% of both groups attained 20/40 or better vision.

There is a 2-10% incidence of cystoid macular edema associated with lens implantation. This condition, characterized by a serous edema of the macula is a major cause of poor visual result. Cystoid macular edema may also be seen after uncomplicated cataract extraction, however, the increased incidence with lens implantation seem to be statistically significant.

Dislocation of the lens implant is not uncommon. Most often a loop or clip may slip in front or behind the iris. The lens may dislocate forward into the anterior chamber, or posteriorly into the vitreous. The anterior dislocation may be especially dangerous due to possible corneal touch, and intractable corneal edema. In the case of dislocations, lenses must be promptly relocated or removed, most often requiring an additional operation.

## Conclusion

Lens implantation has been an important advance in the ophthalmic armamentarium. As with so many new developments in surgery, the risk/benefit ratio must be carefully evaluated to determine if the procedure is in the best interests of the patient.

# School Screening for the Early Detection of Scoliosis in Children

THOMAS S. RENSHAW, M.D., ROSEMARIE GURNHAM, R.N.,
AND JAMES R. GAGE, M.D.

**ABSTRACT—School screening programs have been shown to be effective methods for the early detection of idiopathic scoliosis. Early detection means that fewer children will require extensive surgical treatment. Because this concept has recently been endorsed by the Connecticut State Medical Society and since more and more schools in Connecticut have started screening programs, this article describes the method of school screening for scoliosis and suggests a program of follow-up management.**

Scoliosis, defined as an abnormal lateral curvature of the spine associated with rotation of the vertebrae about their vertical axes, is a common condition that often develops insidiously during a child's rapid growth period. It is not uncommon for scoliosis to progress undetected to significant deformity. There are several reasons why: 1) nearly all cases are painless and produce no other symptoms, 2) the "bashful age" of adolescent modesty precludes parents from seeing their children's unclad spines, 3) routine physical examination of the older child has been supplanted by episodic, problem-related health care, 4) currently popular long hair and loose clothing styles easily conceal significant deformity, 5) lack of professional attention to signs of spinal deformity, and 6) limited public awareness of scoliosis and the common myth that "all adolescents have poor posture."[1]

The prevalence of idiopathic scoliosis in adolescents in most areas of the United States is consistently about 4 percent.[2] Although the natural history of this condition is that most cases do not progress in severity beyond the time of diagnosis, there is ample evidence that untreated progressive scoliosis can lead to significant medical and social problems.[3] Medically, irreversible cardiopulmonary impairment, increasing fatigability, back pain, shortened life expectancy, and marked cosmetic deformity can result. Social stigmata of scoliosis include decreased likelihood of marriage and increased likelihood of unemployment. Most studies agree that between 1.5 and 3 per thousand in the adolescent population have progressive scoliosis of a magnitude requiring active treatment.[2]

School screening programs have been shown to be effective means for the early detection of idiopathic scoliosis so that if treatment becomes necessary, orthotic methods (bracing) can be employed. Such programs very markedly reduce the need for surgical fusion of the spine—a complex, expensive, major procedure with attendant risks, which may be the only way to halt progression in curves too large to be amenable to orthotic control.

In May, 1978, the Connecticut State Medical Society approved a resolution endorsing the concept of statewide school screening for scoliosis. If, as a result, more schools begin screening, it is probable that more children will be referred to primary care physicians for evaluation of a positive screening examination. In some instances, perhaps the physician will not have had a great deal of experience with scoliosis and may have difficulty determining whether or not a curve can be safely followed in the office or if it should be referred for further evaluation or treatment.

The purpose of this article is to describe the method of screening school children for scoliosis and to suggest a means of follow-up for those children in whom the diagnosis is established.

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## Method

Idiopathic scoliosis most often develops between the ages of 10 and 15 years, and it is strongly suggested that these children be screened annually. Schools provide the most complete, efficient, low-cost access to this population group. In addition, school systems have historically supported preventive care programs with visual and auditory screening procedures. A trained screening examiner, most often the school nurse or physical education teacher, can rapidly and accurately perform a simple, comprehensive, reproducible examination with a minimum of resources involved.

Some preliminary groundwork is necessary. The support of the school board, administration, and school physician must first be obtained. Next, the persons doing the examining need to be trained. It is well to inform the parents, the community, and the parent-teacher organizations by way of news releases to the media. Finally, the children should be prepared in advance by presentations such as movies, slide shows, or lectures in assemblies or health classes.

The actual screening can best be done in a school physical education class. Those excused from this class should also be present. The clinical deformities produced by scoliosis can be easily seen once the examiner has gained a little experience. The subject should be examined undressed from the waist up or in a body suit. A bathing suit or bra, however, will not interfere with the examination and may do much to preserve the modesty of a pubescent girl. The student must first stand up straight with back to the examiner, feet together, head up and looking straight ahead, and arms hanging relaxed at the sides. The examiner looks for: 1) asymmetrical shoulder levels, 2) prominence of one scapula, 3) unequal distances from the arms to the chest wall, 4) a palpable lateral curving of the spinous processes, 5) unequal waistline or a high hip, 6) the head centered over the intergluteal cleft, and/or 7) pelvic obliquity or leg length inequality (Figure 1).

Next and the most important assessment is the forward bending test. With feet together and knees straight, the child bends to nearly 90 degrees at the hips with the arms dangling forward, palms together. Viewed from behind and again from in front, both sides of the chest and both sides of the lumbar area should be at the same levels. The most consistent early sign of scoliosis is an asymmetrical prominence on one side of the thoracic or lumbar area. This is caused by the vertebral rotation that usually accompanies scoliosis. Lateral deviation of the spinous processes may also best be seen in this position (Figure 2). In addition, abnormal degrees of juvenile kyphosis or postural roundback can be detected during the screening examination. The forward bending test completes the screening and it is then essential that an accurate record be kept for each child. During the early stages of a screening program, it may be a good idea to have initial positives rechecked with the screener being aided by a more experienced person before referral is made.

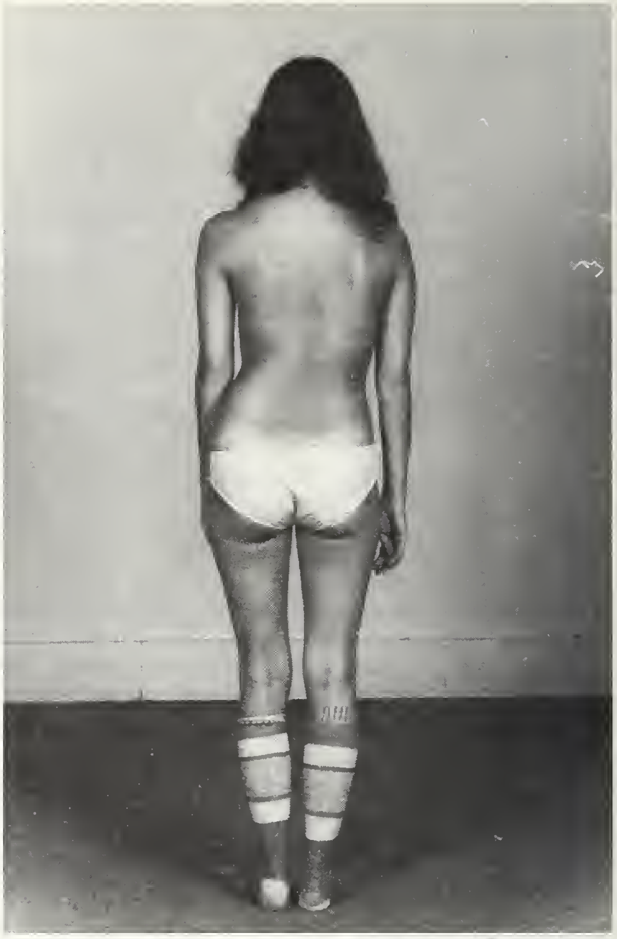

Figure 1

This student has the physical signs of scoliosis: 1) asymmetrical shoulders with unequal scapular prominence, 2) unequal arm-to-chest distance, 3) lateral spinal curvature, 4) an unequal waistline, and 5) head not centered over intergluteal cleft.

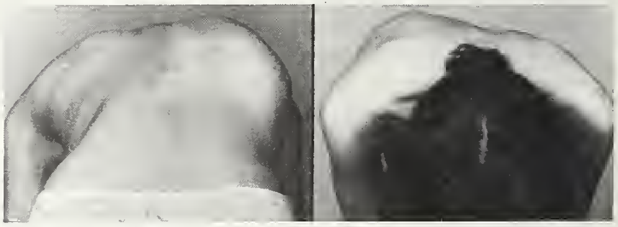

Figure 2

The forward bending test demonstrates asymmetry of the chest and lumbar regions as well as right lateral deviation of the spinous processes.

When a screening examination is positive the parents should be informed by a letter or phone call emphasizing the need for prompt follow-up evaluation by the patient's pediatrician, family physician, or an orthopaedic surgeon. Later, a second contact with the family should be made to assure that compliance with follow-up has occurred.

### Follow-Up

If the patient's physician confirms the suspected scoliosis by his own physical examination, he should obtain and measure a *standing* anteroposterior roentgenogram of the entire thoracolumbar spine. A method of measurement is shown and described in Figure 3. Clinically-apparent scoliosis occurs with nearly equal frequency in both sexes. In those patients requiring treatment, however, girls outnumber boys by a factor of about 7 to one.[4] Therefore, adolescent girls with idiopathic curves greater than 10 degrees are at relatively high risk for curve progression, particularly if significant vertebral rotation is present. Relative thoracic lordosis (less than 20 degrees of roundback) is another poor prognostic sign.

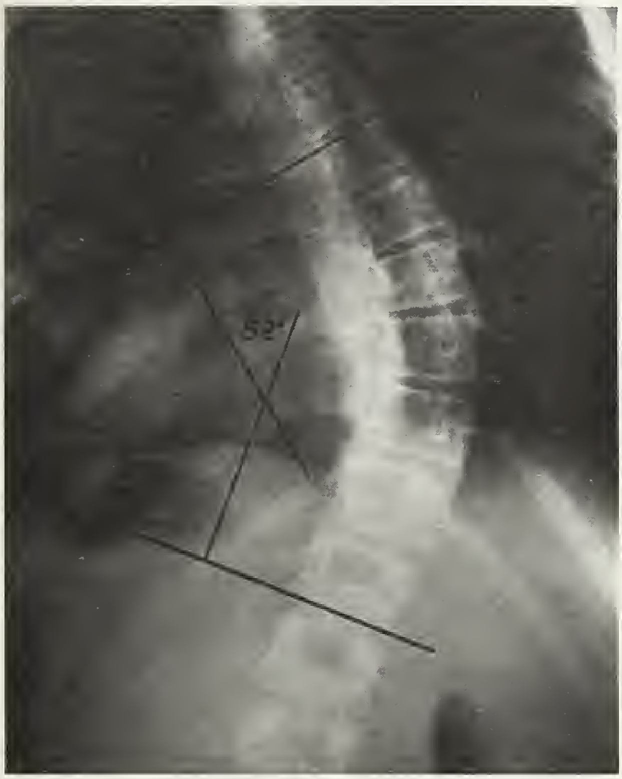

Figure 3
The Cobb method for measuring scoliosis. The proximal and distal end vertebrae are those that tilt maximally toward the concavity of the curve. Parallel lines to the proximal vertebra's superior cortical end plate and the distal vertebra's inferior cortical end plate are drawn. If these lines do not intersect on the film, perpendiculars are erected and the intersecting angle is the angle of the curve.

It is suggested that scoliosis of less than 10 degrees can safely be followed by the primary care physician unless some unusual circumstances prevail. In curves of less than 10 degrees, as long as there is no progression of the clinical deformity, e.g., increase in rib or lumbar prominence, shoulder discrepancy, scapular prominence and/or pelvic obliquity, roentgenograms may not be necessary at each subsequent visit. The amount of clinical deformity can be quantitated by clinical measurement or photography and should be recorded at each visit. The child with idiopathic scoliosis should be seen at 3- to 6-month intervals throughout the active growth years and a roentgenogram should probably be reviewed at least every 6 months. Curves of greater than 10 degrees in a growing child probably should be referred to an orthopaedic surgeon. This is particularly true in a female, if there is significant clinical deformity, or if there is a family history of progressive scoliosis, since these children are at higher risk for progression.

Treatment must be individualized for each patient, but general guidelines may be helpful. These are: 1) most nonprogressive curves and most curves of less than 20 degrees may be safely followed by observation and documentation, 2) progressing scoliosis of between 20 and 40 to 45 degrees should be treated with an appropriate orthosis and 3) curves of 45 degrees or greater are usually best treated by spinal fusion.

### Conclusion

Idiopathic scoliosis is a common spinal deformity, frequently seen in the preadolescent or adolescent. It is almost always responsive to conservative treatment, provided that the diagnosis is made before the curve has reached too great a magnitude to be controlled by nonsurgical methods. It has been shown that school screening programs for scoliosis can reduce or nearly eliminate the need for extensive spinal fusions in such children.

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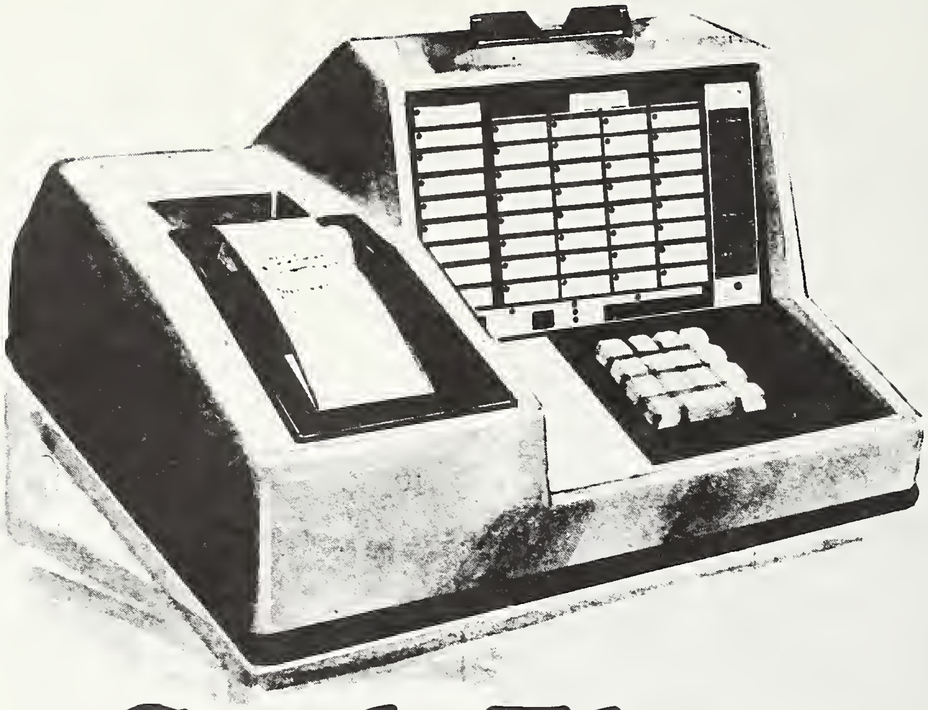

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# Computerized Tomography in the Assessment of Cerebellar Atrophy

## Computerized Tomographic Case of the Month

SIDNEY GLANZ, M.D. AND STEPHEN L.G. ROTHMAN, M.D.

### Introduction

The diagnosis of cerebellar atrophy may be difficult to establish on clinical grounds alone. The question of a posterior fossa mass often enters into the differential possibilities. Prior to the advent of CT scanning, pneumoencephalography was required in order to make a definitive diagnosis. The CT scan offers a rapid, non-invasive method for diagnosis.

### Case Report

A forty-three-year-old white male presented with a history of mild gait ataxia and dysarthia for the past three years, both of which had become progressively worse over the past six months. The patient had a known seizure disorder since childhood, which was well controlled with dilantin and phenobarbital. This was no history of alcoholism or drug abuse.

Physical examination revealed slurring of speech, intermittent nystagmus, mild heel to shin ataxia, and wide based gait. The remainder of the examination was unremarkable. The differential diagnostic considerations were primarily cerebellar atrophy versus a mass lesion in the posterior fossa.

A CT scan was performed (Figure 1). The scan demonstrated a markedly enlarged superior cerebellar cistern, with an atrophic vermis and enlarged cerebello-pontine angle cisterns. No masses were identified. These findings were compatible with a diagnosis of cerebellar atrophy, and the patient has been clinically followed.

### Discussion

There are numerous etiologies of cerebellar atrophy. The syndrome of olivopontocerebellar atrophy presents with a specific clinical picture. The pneumoencephalogram usually reveals enlargement of the subtentorial subarachnoid spaces, enlargement of the fourth ventricle, prominent interpeduncles and pontine cisterns, and small cerebellar folia with deep wide sulci. Hypoplasia of the cerebellum may occur as an isolated entity, although it is usually associated with generalized brain mal-development. Toxic cerebellar atrophy is usually associated with chronic alcoholism. The major pathologic change is degeneration of the cerebellar cortex, particularly of the anterior and superior aspects of the vermis. The prolonged use of dilantin has also been reported as a cause of cerebellar atrophy.

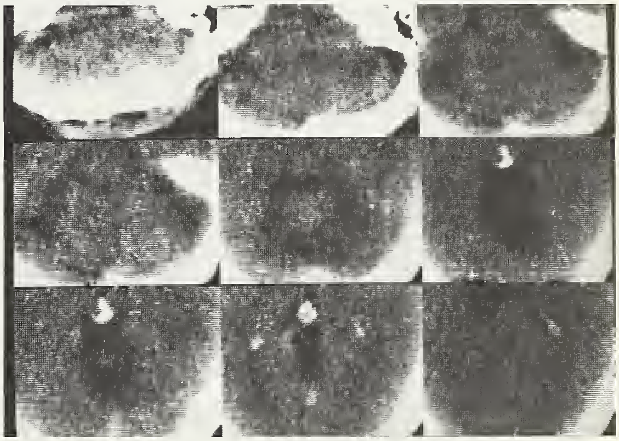

Figure 1

Nine consecutive CT sections of the posterior fossa showing (1) enlargement of the superior cerebellar cistern (2) wide lateral subarachnoid spaces (3) normal fourth ventricle.

CT findings are essentially the same as those described with pneumoencephalography. Enlarged superior cerebellar cisterns, fourth ventricle and cerebello-pontine angle cisterns, and prominent cerebellar sulci are the most common findings.

The presence of these abnormalities on a CT scan, without evidence of a mass in the posterior fossa, allows the clinician to make a diagnosis of cerebellar atrophy quickly and non-invasively.

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# A Surgeon's Response to Congress

SHERWIN B. NULAND, M.D., F.A.C.S.

***House Unit Finds Unneeded Surgery Still Rampant***
**Headline, *New York Times,* December 27, 1978**

We stand accused. The press, the public, our chosen representatives in the halls of Congress, and worse—our own patients, line up against us. They are puffed up in their self-righteousness by an air of authority that is culled from the pages of our own most esteemed scientific literature. Their anger is justified and given weighty dignity by the magic of the same kind of statistical analysis that we ourselves use in clinical medicine. The numbers and figures are there for all to see—they scream forth from the pages of the *New York Times* with a certainty that defies disbelief and challenges refutation. The Congressional staff members who accuse us invoke the ancient Atonement prayer to tell us that we have lied, we have dealt treacherously, we have been stiff-necked, and finally that we have indulged ourselves, for profit no less, in something called Unnecessary Surgery.

In the midst of the storm of accusations, the trial-by-newspaper and the pre-emptive verdict, we stand publicly mute, effectively unresponsive. Only in O.R. locker rooms, at scrub sinks, and around nurses' stations do we protest. The protests are mumbled or shouted, humble or indignant, frightened or bold, but always outraged, and always, nevertheless, inarticulate.

Surgeons are strange birds. We are seen by our medical brethren as rigid, opinionated and overbearing. A surgical chairman at a great university (Duff and Hollingsworth once called the place "Eastern," when they wrote *Sickness and Society)* tells us that surgeons have what he calls "very strong egos." We would like to believe that, but our psychoanalytic colleagues know better, and in our darkest moments, so do we.

But whether sure of ourselves or shaky, strong-egoed or pusillanimous, one thing we are for certain is inconsistent. The careful, objective and (yes) compulsive way in which we evaluate information in the clinical setting is abandoned when that setting is changed to the socio-economic background against which we practice our art. Our strict attention to the data in our literature and our dependence on facts, facts, facts before venturing an opinion blow away in fuzzy gray smoke when that literature becomes the lay press.

We have been stampeded needlessly. Had we as carefully examined the unnecessary-surgery literature before accepting guilt and paranoia as we did, for example, the cancer literature before accepting the concept of modified breast surgery, we would not be finding ourselves in the prisoners' dock in 1979. How many of us have actually read Dr. McCarthy's original indictment,[1] published four years ago in this country's most prestigious medical journal? Of those who have read it, how many fewer have looked at the data, and the methods used to gather those data? How many have paid attention to the manner in which the Moss Committee has misused and misinterpreted the study to press our prosecution? How many, therefore, will really know whether we are guilty as charged?

Our indictment deserves review, a review in which we should pay our usual scrupulous attention to detail before making a diagnosis, even though we ourselves are being denounced as the etiological agents.

The fire was lit by Dr. Eugene G. McCarthy of the Cornell Department of Public Health in 1974, as follows: each member of a group of 1,356 patients who had been told by his own personal physician or surgeon that an operation was necessary was sent to a qualified surgical consultant, who was asked to evaluate the patient and to state whether, in his opinion, surgery was indicated. The result was that, in the words of the study's abstract, "24% of all procedures recommended were not confirmed,"

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SHERWIN B. NULAND, M.D., Assistant Clinical Professor of Surgery, Yale University School of Medicine; Literary Editor, *Connecticut Medicine.*

ranging from approximately 16% for general surgical problems to 40% for orthopedic disorders. A later report in 1978 produced similar results, in a much larger group of patients.[2]

Although Dr. McCarthy and his collaborator, Geraldine W. Widmer, R.N., MPH, warned that "the findings in this report should be considered preliminary," and furthermore that "as a result of a number of factors, the findings presented here cannot be applied to the general population undergoing elective operations," the stampede was on. The figures were used by the Moss Committee, (appropriately called the Subcommittee on Oversight and Investigations) as evidence that a significant proportion of surgery in the United States is unnecessary, and worse. If one takes the national figures for postoperative deaths, as Moss did, calculates the percentage of those deaths due to "unnecessary operations," one comes up with a truly horrendous carnage perpetrated on a victimized public by the Horsemen of the New Apocalypse, us. And all of it quite obviously for profit.

The facts are clear—clear enough so that any reader of the *Daily News, Cosmopolitan Magazine* or the *New York Times* can grasp them while hanging from a subway strap: If McCarthy's doctor number 2 disagrees with doctor number 1, that initial profiteer must have recommended unnecessary surgery. Doctor number 2 is, after all, a consultant, often a professor, and therefore has no profit motive, while doctor number 1 is a surgeon who cuts for money. Because the two doctors disagreed one time in four, this must mean that approximately one in four surgical procedures in this country is obviously unnecessary (ergo, one in four postoperative deaths as well), and that people must be saved from the unscrupulous doctors who do them and remain conscience-clear when many of their victims die.

We have been exposed to all of the New York literati, from shipping clerks to atomic physicists. Every group from the elderly nocturics (37% of urologic operations are unnecessary, we are told) to the radical feminists (1/3 of gynecologic procedures need never have been done) has it in for us. And rightly so. If we are guilty, we should pay the price of our criminal avarice.

But a small beginning in assessing guilt can be made by a careful evaluation of the studies upon which the charges are based, and of the conclusions that have been drawn from them. We can do this using the same methods of evaluation as we would for any other study in clinical medicine. We begin with the raw data, evaluate the experimental methods and try to determine if the conclusions are supported by the data and the methods. Having determined the validity of the conclusions, we can assess what action is to be recommended. It is an old technique; it is the only technique. We have all been using it since medical school, even if the congressmen and the journalists have never heard of it. There is no other way to comprehend the mass of information and interpretation that science and everyday life throw at us. There is no other way to stay clinically sane.

Let us make a beginning by examining the way in which the term "unnecessary surgery" is defined. As noted above the Moss Committee and the press define an unnecessary operation as one that has been recommended to a patient by his physician, and which a qualified surgical specialist then tells him should not be done. Our inquisitors may not realize that this is their definition, but since the figures come from Dr. McCarthy's studies (McCarthy himself never uses the term, preferring the less overtly obnoxious "not confirmed"), their possible ignorance is no excuse for erroneous charges.

Now, what has been done with the data is as follows: if, for one-quarter of the patients the specialist says that the operation is not indicated, the congressional committee then bellows to the headline writers that 1/4 of the surgery done in this country is therefore unnecessary. This is quite an olympian leap, and presupposes two conditions:

(a) That the first physician is a surgeon and quite prepared to do the recommended operations, and
(b) that the consultant is correct, and not simply having a legitimate difference of opinion with his colleague.

To study the second supposition would require carefully designed studies that include long-term follow-up of all patients, evaluation of the basis upon which both positive and negative recommendations were made, and some determination of how each of the two recommenders felt about the validity of each other's arguments. So far none of this has been done, even though Dr. McCarthy continues to publish data, and even though more than four years have gone by in which such studies could have been carried out.

The first supposition, however, is easily disposed of. Because I have always suspected, and have in fact been informed by a source close to the original study, that the first pro-surgery opinion was often given by a non-surgeon, I wrote to Dr. McCarthy a few months ago to find out exactly how often a board-certified surgeon was the original recommender. His reply[3] described the 1978 report, and stated that in the group (3,827 patients) in which a second opinion was voluntary, only 53% could be shown to have had the original opinion rendered by a board-certified surgeon. In the group (3,131 patients) in which the second opinion was mandatory, the figure was 61%. Nevertheless, in his letter to me, Dr. McCarthy ignores his own figures by stating that "in general, participants in the Cornell second opinion study initially are recommended for surgery by a board certified surgeon." He compounds the statistical legerdemain by referring, as he did at the April, 1978, meeting of the American Surgical Association to[2] "the first physician—who, in the vast majority of cases, is a surgeon."

The facts, of course, are quite otherwise. The McCarthy figures actually do us credit, if our journalistic and legislative critics would only look at them. They tell us that at least 1/3 of the time (and probably more often) it is a *non-surgeon* who initially recommends the operations, and a *real surgeon* (defined as one who is board certified) who says no. In actual fact, McCarthy is showing us that it is the board qualified surgeons themselves who have been the best defense against unnecessary surgery. This is something we have always recognized by simple observation and experience; it is rewarding to have it proven by our biometrically-minded colleagues. It is a clear conclusion, quite opposite to the erroneous one with which McCarthy, Moss and Media have been flagellating us.

Who is to blame for this misrepresentation? First, of course, are the original researchers from Cornell. In their 1974 paper they described the source of information about the proposed surgery as the "personal physician" and then, six paragraphs later, describe the two recommenders as "the original and consulting surgeons." Since many of the original physicians were clearly not surgeons, this sort of writing indicates sloppy terminology at best and deliberate obfuscation at worst. What is important is that the researchers have left the non-critical reader with the impression that a second surgeon was disagreeing with a first *surgeon* approximately 24% of the time, and that the second surgeon is always right. At least the first half of this conclusion is patently untrue, and the second half would almost certainly not stand close scrutiny if analyzed as suggested earlier in this essay.

The McCarthy researchers compounded this sort of confusion in their American Surgical Association presentation by juxtaposing groups of patients in which the first doctor *was* a surgeon with groups in which he *may or may not have been,* bewildering the issue beyond retrieval. Having thus associated a few apples with a few pears, their paper leaps directly into the *Discussion* section in which they gratuitously tell us of other published studies indicating that there is "a surplus of surgeons for the needs of the population and that this has led to excessive surgery." They also point to researches that "support the hypothesis that surgical rates are related to the supply of surgeons." By following their blinding array of data with such unrelated editorial statements masked as *Discussion,* they imply that these charges are a natural outgrowth of the figures in the first portion of the paper. The reader should be wary of this poorly laid trap of non sequitur, non-scholarly gibberish.

Their paper goes on to tell us that second opinion studies have produced what they refer to as the "Sentinel Effect"—by which they mean that their own judicious and authoritative scrutiny has frightened us inadequate surgeons away from taking advantage of our patients quite as frequently as formerly. They do not hesitate to remind us, again gratuitously and with pompous self-righteousness, that "it is evident that inadequate training and ethically questionable motives may result in inappropriate surgery." One might add, perhaps equally gratuitously, that inadequate statistical research and questionable interpretation (and, oh yes, motivation, too) may result not only in inappropriate conclusions, but outright slander.

Please read the paper. Perhaps you may be able to tell the rest of us how the statements in the *Discussion* are justified by the figures presented in the preceding sections. It is a type of sophistry that belongs in the political arena, but which has no place in a scientific journal, and no claim to scientific validity.

Well, the next step was obviously inevitable—the step that did indeed take all of this out into the great world of politics. Dr. Francis Moore[4] tells how it happened, as follows:

"Some junior staff members of the Moss Committee . . . were very anxious to demonstrate for their boss (Moss) a very high level of unnecessary expense and mortality arising from fraudulent surgery. They, therefore, grasped the difference of opinion level and the incidence of this disagreement, and extrapolated it to the number of unnecessary operations. This is an extrapolation fostered by careless statements in Dr. McCarthy's first article. We believe that it is a preposterous extension and that you just cannot get there from physician disagreement. Then, as if to compound the felony, these same junior staffers picked out some mortality figures from a very special cohort of patients studied by Dr. Child in the "Critical Incident Study" in the National Surgical Study, and extrapolated these mortality figures to the entire array of elective surgical operations. Imagine getting there from a level of physician disagreement. The whole concatenation of misunderstandings (a polite word for deliberate falsification by junior congressional staff helpers) has been so well ventilated that we will spend no more time on it here."

Dr. Moore attacks the McCarthy study for its attempt to "condemn disagreement or extrapolate from healthy disagreement the incidence of fraud and/or the unwise expenditure of public moneys."

So there it is. The Moss Committee views us still with alarm. Its newest estimate (December, 1978) is of two million unneeded operations in 1977, a consequent loss of ten thousand lives and a cost of four billion dollars. They have also misunderstood the meaning of the Child study of surgical complications, and distorted that carefully researched self-scrutiny into yet further proof of our homicidal tendencies. The *New York Times,* in repeating the conclusions of these our congressional overlords, goes so far as to publish the telephone number of a toll-free hot line (800-325-6400; in Missouri 800-342-6600) to help second opinion seekers find a consultant certified by HEW to be "qualified."

It has been more than a little difficult, as I have tried to put the foregoing into some kind of understandable sequence, to avoid an occasional sardonic sneer, each one of which seems to have found its way into the text. Good taste demands an apology, but this essay has not been written with good taste in mind. It has been written with objectivity in mind, and with some attempt to put our surgical paranoia into accurate perspective.

No one doubts that there are some unnecessary operations, just as no one doubts that there are some patients who badly need operations and yet never have them. But no purpose will be served by misinterpretation of data or by obfuscation of conclusions, whether deliberate or not. Perhaps as important is the observation that no purpose will be served either, and no problems will be solved, by our outraged posture of defensiveness if we do not examine the charges against us, evaluate the data and seek the truth. Politicians will always pragmatically use what they can in any way that seems appropriate at the moment. Their ascent to power is frequently unrelated to the search for truth, and, for all we know, may sometimes be impeded by it.

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In your behavior to the sick, remember always that your patient is the object of the tenderest affection, to someone, or perhaps to many about him; it is therefore your duty, not only to endeavor to preserve his life, but to avoid wounding the sensibility of a tender parent, a distressed wife, or an affectionate child. Let your carriage be humane and attentive, be interested in his welfare, and show your apprehension of his danger, rather by your assiduity to relieve, than by any harsh or brutal expressions of it. On the other hand, never buoy up a dying man with groundless expectations of recovery, this is at best a good natured and humane deception, but too often it arises from the baser motives of lucre and avarice: besides, it is really cruel, as the stroke of death is always most severely felt, when unexpected; and the grim tyrant may in general be disarmed of his terrors, and rendered familiar to the most timid, and apprehensive; either by frequent meditation, by the arguments of philosophy, or by the hopes and promises of religion. But even overlooking the important concerns of futurity; the business of this life may render such a conduct highly dangerous and criminal; as those to whom the thoughts of death are painful, are too apt when flattered with the prospect of recovery, to neglect the necessary provision against a disappointment, and by that means involve their families in confusion and distress.—Samuel Bard, M.D., Professor of the Practice of Medicine in Kings College, (Columbia University) Commencement Exercises, May 16, 1769.

# New Initiatives in Health Care Legislation

CONGRESSMAN PAUL G. ROGERS

President Hamburg, distinguished members of the Institute of Medicine, I am delighted to be with you and am pleased to share some perspectives on health legislation—now and in the future.

It's fascinating to look back over the past 25 years—as of course I have inevitably done in recent weeks—and consider the strides that have been made in health law as well as the considerable changes that have taken place in the Congress itself.

When I first became interested in health legislation, most bills were initiated by the Executive Branch or at least developed only in close consultation with the Executive Branch. As a general rule, Congress responded to presidential initiative rather than responding to problems in health as an independent branch of government. There were exceptions of course—Hill-Burton, migrant health and others—but, by and large in earlier years, Congress played the role of reactor rather than initiator.

Small wonder. When I assumed the chairmanship of the Health Subcommittee in 1971, do you know how many staff members there were serving the House Commerce Committee for health legislation? The answer is one. The Executive Branch not only initiated the laws, but it did most of the research on the laws, wrote the lion's share of the committee reports on the laws and orchestrated their passage through the Congress.

For several reasons this is no longer the case. Principally because of the breakdown in relations with the Executive Branch which occurred five years ago and the radical difference in philosophy between the Congress and the Executive Branch with respect to the need for health legislation that occurred in the early 1970s, Congress forced itself to acquire more independence and more expertise. The staff of the health subcommittee now numbers eleven. Legislation is now written on the Hill. Much of the legislation now on the books was not only not initiated by the Executive Branch, but was actively opposed by the Executive Branch. In short, the Congress acquired an independence, an expertise, and a willingness to legislate, if necessary without Executive Branch involvement.

A second major change in the Congress has been a requirement that we legislate in the open—in the sunshine—and not behind closed doors. Frankly, I was apprehensive that we wouldn't get much done in open subcommittee deliberations, particularly if our friends from the press were there. I'm delighted that I was wrong. While openness has slowed down the legislative process somewhat—a factor that some in this room wouldn't think is such a bad idea—it has meant that members of Congress are better prepared, more eager to debate, more able to present facts. In my judgment, the produce—legislation as reported from subcommittee—has improved considerably as a result.

Third, the nature of legislation has changed. Legislation is becoming more complex—partially because of the need in prior years to write it more precisely in order that it be implemented in accordance with the intent of Congress, and partially because—as you well know—the medical field is so much more complex than it was a few years ago.

Thus, today, health legislation not only is providing funds for health services, it is beginning to take on a regulatory approach, and in my view, the emphasis on regulation will continue throughout the 1970s. In areas such as Medicare and Medicaid in which there is a heavy federal investment and in areas in which the safety and quality of health care products have become questionable, the public is demanding greater assurance by government and is receiving these assurances in the form of government regulation.

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CONGRESSMAN PAUL G. ROGERS (D) was elected to the 84th Congress from the Eleventh District of Florida in a special election on January 11, 1955. He subsequently was elected to each succeeding Congress through the 95th Congress. He is retiring as head of the House Commerce Health Subcommittee. His proposed National Coalition for Disease Prevention will be a broad-based coalition of health and environmental groups aimed at disease prevention.

This speech was delivered at the annual meeting of the Institute of Medicine in the Fall of 1978.

What are the health laws I'm most proud of, that will have their greatest impact on health?

First, I believe the most important health measure enacted by the Congress this decade is the Clean Care Act. The 1977 amendments to the Clean Air Act, to which we devoted more than three years in development, had as their foundation the 1974 study of the National Academy of Sciences, which estimated that 15,000 premature deaths result annually from air pollution, that air pollution causes 15 billion person days of restricted activity each year, and that reducing air pollution to the levels of the national health standards would save from 3 to 13 billion dollars each year.

I vividly remember one of the subcommittee's first non-Washington adventures—to Birmingham, Alabama—during the time that the emergency provisions of the Clean Air Act were invoked. Several of us on the subcommittee flew directly over North Birmingham, and witnessed first hand the yellow fumes trapped by a temperature inversion—fumes that were taken into the lungs of the vast majority of residents of that city. Everyone in health should have that experience—they would instantly learn from it that the Clean Air Act has as its foundation the health of human beings. It is, I believe, the most important health measure to which I've had a chance to contribute.

Second, the National Cancer Act. In 1971, Congress mounted a drive to intensify research efforts against cancer. That drive continues today. Although many feel that cancer research has more than its fair share, I can assure you that the American public—that pays the bills—does not.

But the feature of the 1971 legislation of which I'm most proud is this: The final version of the Act—predicated on the House bill—preserved the integrity of the National Institutes of Health, the greatest research institution in the world. To have separated the National Cancer Institute from the NIH would have fragmented our country's biomedical research effort. It almost happened—but it didn't.

Third, health planning. Health planning legislation was a true congressional creation—crafted during the time that Congress and the Executive Branch were at odds. Despite this, in 1974 we emerged with a bill that holds the promise of bringing order to the distribution of health care resources in this country. I believe that in only a few years, HSAs will become a major factor in the control of skyrocketing health care costs and the rationalization of the delivery of health services.

Fourth, despite a few glitches [errors] here and there, I'm extremely proud of the role of health manpower legislation in encouraging medical educators to meet the demands of the public. I believe that the 1971 and 1976 health manpower laws have results in substantial inroads on geographic maldistribution of health professionals and start toward correcting a severe national shortage of primary care physicians. It has set the stage for federal funding of medical residency training not simply because a training slot exists—but because it is needed.

Finally, Medical Device Legislation. Passed almost unanimously in Congress during an era of anti-regulatory feeling, the Medical Device Amendments of 1976 will, in my view, result in safer and more effective medical products. They were intentionally written to insure that industry and consumers can, in a spirit of cooperation, work with government to develop fair regulation. I was criticized in some quarters for the number of advisory committees placed in the law—and the demand that consumer and industry be involved at the time government has to make critical decisions—but continue to believe in a partnership between industry and government in the implementation. I continue to believe that industry and consumers can get in the same room with government and emerge with a consensus that is in the public interest.

What of the future? I foresee a continuation of Congress' proclivity to initiate legislation, in partnership with the Executive Branch. I foresee continuation of the openness Congress has imposed upon itself with success. I foresee the continuation of Congress' commitment to assure access to health care services to those who are either geographically or financially remote from such care. And I foresee the continuation of Congress' proclivity to enact complex legislation, regulatory in nature.

I also foresee, with your continued support, a partnership between the Congress and the Institute of Medicine in insuring the effective evaluation of health legislation. In the 95th Congress alone, the Health Subcommittee commissioned two studies by the Institute of Medicine—one to study the carcinogenicity of food additives in general and saccharin, in particular—the second intended to be the definitive work with respect to the need for federal funding of nurse training. With the increasing sophistication of health care technology and evergrowing complexity of the issues surrounding health care legislation, I predict the Congress will continue to rely heavily on the expertise on the Institute of Medicine to provide advice and counsel.

I leave the House with the assurance that health and environmental legislation is in good hands. My remaining colleagues in the House and Senate charged with legislative initiative are dedicated and skilled. My friends in HEW—headed by a person who I believe will go down as the greatest HEW Secretary ever—are equally adept and respect the law. I know that both branches of government will continue to work with the President of the Institute of Medicine and his staff to pursue excellence in health.

# The FTC Administrative Law Judge's Proposed Order

## FTC vs. AMA, CSMS and NHCMA

*EDITOR'S NOTE: This order is not in effect until it is reviewed by the FTC; even then it would be subject to appeal in the courts. The AMA, CSMS and NHCMA have announced their intention to appeal if necessary.*

### ORDER

### I.

IT IS ORDERED that respondents American Medical Association, Connecticut State Medical Society and New Haven County Medical Association, Inc., and their delegates, trustees, councils, committees, officers, representatives, agents, employees, successors and assigns, directly or indirectly, or through any corporate or other device, in or in connection with the purchase, sale, distribution or delivery of physicians' services in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Restricting, regulating, impeding, declaring unethical, interfering with, or advising against the advertising or publishing by any person of the prices, terms or conditions of sale of physicians' services, or of information about physicians' services, facilities or equipment which are offered for sale or made available by physicians or by any organization with which physicians are affiliated;

B. Restricting, regulating, impeding, declaring unethical, interfering with, or advising against the solicitation through advertising or by any other means, of patients, patronage, or contracts to supply physicians' services, by any physician or by any organization with which physicians are affiliated;

C. Restricting, regulating, impeding, advising on the ethical propriety of, or interfering with the commercial terms or conditions on which any physician contracts or seeks to contract for the sale, purchase or distribution of his or her professional services;

D. Restricting, interfering with, or impeding the growth, development or operations of any prepaid health care delivery plan or of any other organization which offers physicians' services to the public, by means of any statement or other representation concerning the ethical propriety of their operations, activities, or relationships with physicians; and

E. Inducing, urging, encouraging, or assisting any physician, or any medical association, group of physicians, hospital, insurance carrier or any other nongovernmental organization to take any of the actions prohibited by Paragraphs A through D above. *Provided,* however, that nothing in this Order shall be construed to prohibit respondents, their constituent or component organizations or their members from reporting in good faith to governmental authorities any alleged violation of law, including but not limited to:

(1) Reporting to appropriate governmental authorities any advertising, solicitation or representation by a physician which they have a reasonable basis for believing is false or deceptive, along with the basis for such belief;

(2) Reporting to appropriate governmental authorities any case of uninvited, in-person solicitation of actual or potential patients who because of their special circumstances are vulnerable to harassment or duress. *Provided, further,* that after this Order has become final for two years, nothing herein shall prohibit respondents from formulating, adopting and disseminating to their constituent and component medical organizations and to their members ethical guidelines governing the conduct of their members in respect to advertising and solicitation activities, if respondents first obtain permission from and approval of the guidelines by the Federal Trade Commission.

### II.

IT IS FURTHER ORDERED that respondents:

A. Serve a copy of this Order by mail upon each of their present members and upon each constituent and component organization of respondents, within sixty (60) days after this Order becomes final.

B. Provide each new member of each respondent and each constituent and component organization of respondents with a copy of this Order at the time the member is accepted into membership.

C. Remove from respondent American Medical Association's Principles of Medical Ethics and the *Judicial Council Opinions and Reports,* and from the constitution and bylaws and any other existing policy statement or guideline of respondents, any provision, interpretation or policy statement which is inconsistent with the provisions of Part I of this Order.

D. Require as a condition of affiliation with any respondent that any constituent or component organization agree by action taken by the constituent or component organization's governing body to be bound by the provisions of Part I of this Order.

E. Terminate their affiliation with any constituent or component organization which, after the effective date of the Order, to respondents' knowledge engages in any act or practice prohibited by Part I of this Order.

### III.

IT IS FURTHER ORDERED that, within sixty (60) days after this Order becomes final:

A. Respondent American Medical Association publish a copy of this Order in the *Journal of the American Medical Association* and in *American Medical News;*

B. Respondent Connecticut State Medical Society publish a copy of this Order in *Connecticut Medicine;* and

C. Respondent New Haven County Medical Association, Inc. publish a copy of this Order in *Issues and Insights.*

### IV.

IT IS FURTHER ORDERED that respondents, within ninety (90) days after this Order becomes final, file a written report with the Federal Trade Commission setting forth in detail the manner and form in which they have complied with this Order.

Ernest G. Barnes
*Administrative Law Judge*

November 13, 1978

# The New Life-or-Death Choices

RUDOLF KLEIN

Like every medical care system in the world, Britain's government-run National Health Service faces a chronic dilemma—whether to use the new life-saving techniques being perfected by science and technology in every instance, regardless of the quality of the lives that can be saved and the financial costs involved.

A decade ago, for example, British doctors enthusiastically applied new techniques to save babies born with spina bifida. The operations were spectacularly successful, but the surviving infants were severely deformed and dependent upon continual attention. Thus, scientific innovation had contributed to new medical and social problems.

Today, in contrast, most physicians here have abandoned the imperative to save every life, Infants with irremediable abnormalities are left untreated, to die usually within nine months or so after birth. So there has been, in effect, a deliberate decision by the medical profession to be selective.

The profession did not make the decision casually, but went through much debate and discussion. In the end, the physicians reached a consensus that the prevention of anguish comes before the preservation of life. Or, as one pediatrician put it: "A doctor must always ask himself whether he has the right to inflict suffering on another human being and his family."

In other words, the physicians determined that consideration must be given to the burden imposed on others by merely keeping an infant alive, since an incurably handicapped child can destroy a family. That view was endorsed by a group of health-care experts, headed by a bishop, which stated that "the doctor has no ethical obligation to treat cases in which the likely benefits are very dubious."

That particular verdict was delivered in the context of the debate on spina bifida. But the choice for doctors is, of course, more general.

It arises acutely in the elderly and in cases of patients with serious brain damage. In such circumstances, drugs may be able to prolong life, but the life may be one of comatose passivity without hope of recovery or one of excessively painful senility.

Scientific and technological advances have made for hard choices. Not so long ago, pneumonia was known in Britain as the old man's friend, since it acted as a kind of natural euthanasia in carrying away the elderly before they became wreckage. Now it is the doctor's responsibility to play the patient's friend. For in Britain, despite the existence of a health service run under government auspices, there has been no move to interfere with the doctor's right to decide.

Occasionally, as in the discussion about spina bifida, leading figures in the medical profession will join to provide guidance for their colleagues. But neither politicians nor the civil service have ever intervened.

In contrast to the U.S. Congress, Parliament has never tried to establish the right of anyone to receive a particular form of treatment and far less to define which forms of treatment could not be given.

The British medical system, however, does force doctors to confront the broader social implications of their decisions whether or not to treat patients.

The National Health Service operates with a fixed budget and without any open-ended commitment to offer the maximum technically feasible treatment to all. Doctors recognize, consequently, that doing too much for one patient may deprive another. Moreover, since they are paid salaries rather than fees, the physicians have no personal financial incentive in maximizing treatment.

In the case of spina bifida, for instance, it costs upward of $10,000 per year to maintain a child in an institution. That is roughly the cost of maintaining an otherwise normally functioning man or woman on renal dialysis at home.

But Britain must ration its resources for renal dialysis, and it has been estimated that as many as 1,000 people under the age of 60 die every year because there are too few kidney machines to deal with the numbers who need them. Here again, the choice of who is treated by renal dialysis is left to the doctors, who take into account the capacity of the patient to undergo the considerable physical and psychological stresses involved.

One possible conclusion to draw from this is that Britain's National Health Service is inadequately financed, since it actually turns people away to die. But that may be oversimplification.

The United States is more generous than Britain in furnishing kidney machines. Yet there is a good deal of dissatisfaction with the overall quality of medical care in America, and there too the decision to provide kidney treatment for everyone may mean denying other resources to patients.

In my estimation, perhaps the correct conclusion is that Britain, being a relatively poor country, has been compelled to become a pioneer in making the difficult choices in the field of medical care—and that other countries will sooner or later have to follow the example set here.

For it is quite clear that, given the rising cost as well as scope of technology, a policy of striving to prolong every life could cheat others of the opportunity to improve their chances for an active existence.

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RUDOLF KLEIN, Professor of Social-Policy Studies at the University of Bath, London, England. Reprinted with permission from *The Washington Post,* Aug. 1978.

IMPORTANT MEDICAL DISCOVERY: Leasing equipment from First Bank saves doctors many headaches.

*Richard J. DeMayo, leasing officer at First Bank, and Mrs. Beverly Manlapaz, office manager for Dr. Jesse S. Manlapaz of Danbury, discuss two new electro-encephalographs leased from the bank.*

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# Child Abuse and Neglect: Program Development at the Waterbury Regional Department of Pediatrics

(Second of Three Parts)

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**ABSTRACT—The magnitude and complexity of child abuse and neglect justify a full commitment by hospitals and their personnel to contemporary program development for prevention, diagnosis and management. The experiences of the Waterbury Regional Department of Pediatrics (St. Mary's and Waterbury Hospitals) in the development of a Child Protection Team, Parent Aide Project, community inservice education program and community Collaboration are reviewed.**

The abuse and neglect of children is a biopsychosocial problem of frightening magnitude whose prevention and management are as complex and challenging as any task in human services. In 1962, Kempe, et al.,[1] in the initial description of "The Battered-Child Syndrome," stated that child abuse was a *frequent* cause of permanent injury or death. Hospital and law enforcement surveys conducted at that time revealed a lower incidence of child abuse and neglect than was apparent in a hospital (Colorado General Hospital) where the diagnosis had come to be seriously considered in all cases of unexplained trauma and failure-to-thrive. Professional responses to the "Battered-Child Syndrome" varied from denial and skepticism to energetic mobilization of resources. Subsequent incidence studies have demonstrated that the perspective of Kempe and his colleagues was indeed accurate. The National Center on Child Abuse and Neglect (HEW) estimates that there are approximately 1,000,000 cases of physical child abuse annually, accounting for the death of approximately 2,000 children per year.[2] Gelles,[3] in 1975, examined styles of conflict resolution in a large cross-sectional sample of families and concluded that between 1.4 and 1.9 million children (1 out of every 24 to 33 children) are vulnerable to physical injury at the hands of their parents each year. This striking incidence estimate applies only to physical abuse and not to the remainder of the spectrum of child maltreatment, which includes deprivation of food and shelter, educational and medical care neglect, emotional neglect, emotional abuse, lack of supervision, abandonment and sexual molestation.

The cost to society in both human and financial terms is enormous. It is becoming increasingly clear that maltreated children are substantially at risk for learning problems,[4] behavior problems,[5] juvenile delinquency,[6] adult criminal behavior[7] and abusive and neglectful behavior as parents themselves.[8] While experts may disagree on the primary underlying etiology of the problem—psychological, social, political—and even on the proper name for it—child abuse and neglect, maltreatment syndrome, pediatric social illness—there is agreement that millions of American children are growing up in frightening, insecure enviornments which are taking an incalculable toll in terms of long-term physical and mental health.

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The Connecticut State Legislature passed its first child protection reporting law (PL-73-625) in 1965. Figure I depicts the upward trend in reported physical and sexual abuse cases from 1970 to 1977 in Connecticut.

Many factors are responsible for the increased reporting of child maltreatment in Connecticut. These include: (1) increasing public and professional awareness of the problem; (2) institution of a fine (up to $500) to mandated reporters for non-compliance with the law (1972), and (3) establishment of the Child Abuse Care-Line (1973). There may, of course, be an actual increase in the incidence of child abuse and neglect.

In 1977, a total of 9,021 children were reported to the Connecticut Department of Children and Youth Services (DCYS) as suspected maltreatment cases. Of these, 5,792 were for neglect, 2,777 for physical abuse and 452 for sexual abuse (distributed statistics, DCYS, 1977). With a state population of 950,000 children under age 18, there was one reported maltreatment case for every 105 children in Connecticut. Making statistical adjustments for an estimate of at least 50% under-reporting[9] and a case report confirmation rate of 70% (personal communication, Director, Protective Services, DCYS), it is reasonable to estimate that one child in 75 under age 18 is being maltreated in Connecticut annually.

With increasing attention to child abuse and neglect in recent years, a myriad of approaches to prevention have been employed. While it is not essential that a hospital be the "lead agency" in a coordinated approach to prevention and treatment, a well organized medical component is crucial to the functioning of any community program. It has been the case that community and university hospitals have frequently taken the leadership role in the development of child abuse and neglect prevention programs. This paper will describe the efforts of a community pediatric program, the Waterbury Regional Department of Pediatrics, and will explore the wide variety of ways that hospitals and their personnel can contribute to the strengthening of families and the protection of children.

### The Waterbury Regional Department of Pediatrics

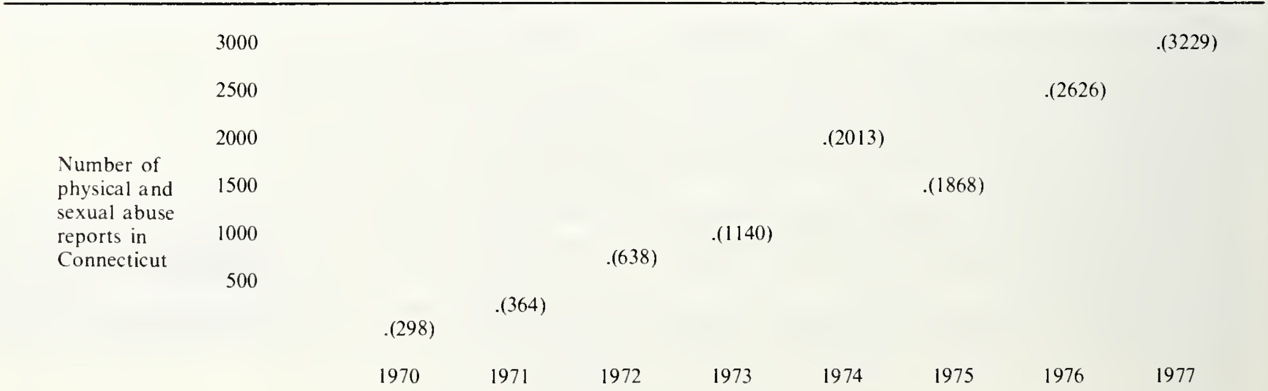
### Early Attempts at Program Development

The Waterbury Regional Department of Pediatrics (WRDP), a pediatric department encompassing the St. Mary's and Waterbury Hospitals and affiliated with the University of Connecticut School of Medicine, was established in 1974. It soon became apparent within the community that there were a large number of families with significant psychosocial problems. Many of the children in these families were being abused or neglected in a variety of ways. During the Department's first year, there were 37 admissions to Waterbury Hospital for abuse or neglect. Data from the Pediatric Ambulatory Care Unit at St. Mary's Hospital revealed that there were approximately 2,000 Outreach transactions per year for families that were viewed as being "at risk" for maltreatment.[10] At the outset, there were no interagency linkages of any kind and no internal hospital guidelines for the management of these complex cases. The relationship between hospital personnel and Protective Services was territorial and occasionally quite hostile. Insights from multi-agency personnel into a given family's functioning were not integrated into treatment planning. Resources were limited to traditional unidisciplinary case management approaches by overworked and undertrained Protective Services workers, traditional mental health services and two community hospitals with no systematic approach to maltreatment problems. Completely absent were multidisciplinary teams, hospital management guidelines, inservice education programs, Parent Aides, Parents Anonymous, infant day care, emergency Homemakers, perinatal surveillance programs, community councils and adolescent shelters.

In 1974, the Family Service Association of

Figure 1

PHYSICAL AND SEXUAL ABUSE IN CONNECTICUT



Waterbury applied to the Connecticut Department of Mental Health for funding for a special infant day care center which would couple day care for children under age three with counseling for their parents. The Regional Health Planning Council rejected the proposal because it did not include linkages with other children's agencies, e.g., Protective Services, Department of Pediatrics, Child Guidance Clinic, etc. In response to the issue, however, the Health Planning Council developed a Child Abuse Task Force comprised primarily of consumers, but with some professional input. This Task Force devised a community plan which did not resemble or apparently recognize successful child abuse and neglect prevention programs in other parts of the country.

In 1975, the WRDP, independent of the Task Force, submitted an ambitious grant proposal to the Connecticut Department of Mental Health calling for the development of a multidisciplinary team, full-time social workers, Parent Aides, Homemakers, day care, psychiatric personnel and educational programs. Though the project was not funded, the process of organizing the proposal proved to be the first step toward interagency program development and communication. Specific individuals from the WRDP, Protective Services, Public Health Nursing Division, Child Guidance Clinic of Waterbury and other agencies found that they could work together and that they shared many views regarding systems change on behalf of children and families.

### The Waterbury Regional Child Protection Team

Following the leadership of experienced and successful multidisciplinary child protection teams in other parts of the country,[11] [12] the Waterbury Regional Child Protection Team (CPT) began meeting informally in 1975. As is often the case, this system change was inspired by a severe physical abuse case which "fell through the cracks." The Connecticut DCYS, the WRDP and numerous community human service agencies expressed strong support for the group decision-making approach to difficult child protection cases and the CPT's membership and process were formalized in 1976. At this time, DCYS, with federal resources (HEW), funded a Community Coordinator for Comprehensive Emergency Services for Children in Waterbury. Her presence proved to be invaluable, not only for the refinement of the CPT but for the development of the Parent Aide Project and the Waterbury Collaboration for the Prevention of Child Abuse and Neglect (see below) as well.

The standing members of the CPT are (1) CPT Coordinator—this position was initially held by the Pediatrician-Director of the Pediatric Ambulatory Care Unit, St. Mary's Hospital. Recently, a full-time Coordinator (MSW) has been employed with Law Enforcement Assistance Administration (LEAA) funding from the Connecticut Justice Commission. With the exception of the full-time Coordinator, the time of all CPT members is donated "in-kind" by the agencies by whom they are employed; (2) Pediatrician—a full-time faculty member of the WRDP; (3) Psychiatrist—the Child Psychiatrist-Director of the Waterbury Child Guidance Clinic; (4) DCYS Regional Program Director; (5) Supervisor, Waterbury Public Health Nurses; (6) Outreach Coordinator, Pediatric Ambulatory Care Unit, St. Mary's Hospital; (7) Director, Inpatient Social Work, Waterbury Hospital; (8) Supervisor, Waterbury Parent Aide Project; (9) Attorney, Waterbury Legal Aid and Reference Society. The Protective Services caseworker and supervisor are always present at the team meetings and a wide variety of personnel also attend on a case-specific basis, e.g., physicians, nurses, school personnel, police, day care and nursery school workers, psychologists, social workers and attorneys.

The justification for the team approach is based on the understanding, from national and local experience, that the most effective interventions in child maltreatment cases occur when coordinated, comprehensive services are provided to families, and when these services are part of a well-developed treatment plan based on the most accurate and thorough knowledge of children and their families that can be obtained. In recognition of this, DCYS does not view the recommendations of the CPT as a "consultation" but rather as the case disposition. If there is an insoluble disagreement between the Protective Services representatives and other CPT members, an appeal process to the state Director of Protective Services is available. However, since formalization of the CPT in 1976, no case management decision has required an appeal.

The CPT attempts to meet weekly and in 1977 met on 40 occasions. With the recent acquisition of a full-time Coordinator, it is now possible to meet at least 50 times a year on an elective basis and additionally in emergency situations. It has become clear that the CPT is most effective and that its time is best spent with initial case reviews and treatment planning. Because of the demand for new case reviews, follow-up is increasingly becoming the responsibility of "mini-teams." These are chaired by the Protective Services caseworker, who always serves as the case manager, and are attended by the clinical case-specific personnel working with the families. In addition, the parents themselves are often included in the mini-team process.

### Waterbury Parent Aide Project for the Prevention of Child Abuse and Neglect

Several contemporary child protection programs across the country have employed non-professional persons to function as "Parent Aides" for maltreating and "at risk" families. These are maternal, nurturing individuals who become involved over an extended period of time in the lives of deprived parents. The annual report of the Onondaga County (Syracuse, New York) Child Abuse Coordinating Program, a nationally recognized model in child protection, states that "there is a general consensus among the many members of the team involved with the Parent Aides that this is indeed the most viable, useful and necessary service that can be provided in a child abuse case."[13] Recently, the National Center on Child Abuse and Neglect (HEW) reported that 33 collective years of experience from 11 demonstration projects revealed that of all funded modes of intervention, Parent Aides were not only the most effective in terms of low recidivism, but were the most cost-effective as well.[14]

In September 1977, the Waterbury Comprehensive Employment and Training Act (CETA) Administration provided funding to the WRDP for the establishment of the Waterbury Parent Aide Project for the Prevention of Child Abuse and Neglect. The Project presently employs five Parent Aides who develop unique relationships with maltreating parents, serving as parenting role models, advisors in household management, liaisons to community agencies and "lifelines" in times of crisis. As of May 1978, 26 families with 34 parents and 80 children have been served. Of the 26 family referrals, nine were for neglect, five for physical abuse, six for failure-to-thrive, and six for "children at risk." After a somewhat slow start, this program is now oversubscribed with a waiting list of referrals from the community, particularly from the DCYS caseworkers. Examination of individual case records reveals that it is highly probable that at least 26 of the children in these families would require foster placement if it were not for the Parent Aides' intervention. In the fall of 1978, funding for the Parent Aide Project will switch from CETA to DCYS.

### Community Inservice Education Program

As a "spin-off" of the CPT, panels of professionals from different disciplines and Waterbury human service agencies frequently provide inservice education in a variety of settings. These panels not only provide useful specific information, but also highlight the multidisciplinary style that is essential for an effective community response to child abuse and neglect.

### Other Program Development in Waterbury

*The Family Service Association Day Care Center*

With multiple sources of support (CETA, Junior League, United Way, DCYS, volunteers), this center provides day care for high-risk children under age three, coupled with services specifically for parents.

*Parents Anonymous*

Three chapters are presently active in Waterbury. The demand for this unique and highly successful approach is great and further proliferation of local chapters is inevitable.

*Twenty-Four Hour Emergency Homemakers*

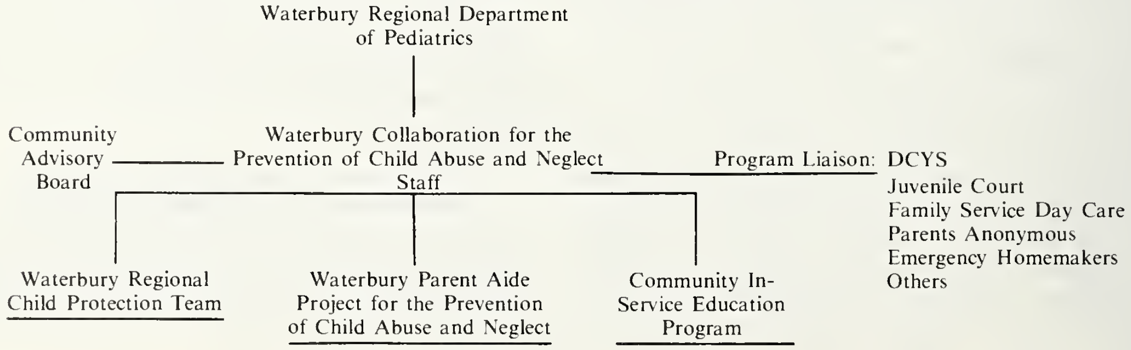
This program has been developed through a Title XX funded project at Source, Inc., and the Waterbury Visiting Nurse Association.

### The Waterbury Collaboration for the Prevention of Child Abuse and Neglect

As program development has evolved, administrative and organizational needs have become increasingly apparent as has been the realization that "in-kind" time is not adequate for the coordination of these programs. To accomplish the integration of the variety of child protection activities in Waterbury, the Connecticut Justice Commission with LEAA (Law Enforcement Assistance Administration) funds and the city of Waterbury have provided the WRDP the resources to establish the Waterbury Collaboration for the Prevention of Child Abuse and Neglect. Full-time staff now coordinate the "Collaboration," whose structure is depicted in Figure II.

Figure II

WATERBURY COLLABORATION FOR THE PREVENTION OF CHILD ABUSE AND NEGLECT


Waterbury Regional Department of Pediatrics
Community Advisory Board
Waterbury Collaboration for the Prevention of Child Abuse and Neglect Staff
Program Liaison: DCYS
Juvenile Court
Family Service Day Care
Parents Anonymous
Emergency Homemakers
Others
Waterbury Regional Child Protection Team
Waterbury Parent Aide Project for the Prevention of Child Abuse and Neglect
Community In-Service Education Program

The authors wish to thank the Connecticut Department of Children and Youth Services, the Connecticut Justice Commission, and the city of Waterbury for their continuing support and are grateful to Patricia Patterson and Marion Rex for their able secretarial assistance.

*Editorial Note:* In next month's issue of *Connecticut Medicine*, this series will continue with a discussion of challenges to program development such as funding, in-kind manpower, territoriality and confidentiality. The spectrum of potential hospital involvement, including primary prevention, secondary prevention, education and child and family advocacy, will be presented.

*(This is the second of a series of three articles.)*

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# Observations on the Canadian Health Care System

## TIMOTHY B. NORBECK

*EDITOR'S NOTE: Mr. Norbeck attended a week long seminar on the Canadian Health Care System in Toronto, Ontario, Canada in November, 1978. His report represents information obtained from various provincial health officials along with his own observations.*

### History of the System

National Health Insurance in Canada is comprised of two separate programs: firstly, the Hospital Insurance and Diagnostic Services Act of 1958; and secondly, the Medical Care Act which followed ten years later in 1968. Several government-sponsored medical-hospital insurance plans had developed in some of the provinces during the 1930's but were never really put into operation. Voluntary insurance programs emerged as well in the late 1930's in the form of hospital association Blue Cross plans, medical association programs, commercial insurance group coverage plans and industrial employee plans.

In 1947, Saskatchewan passed a Province-wide hospital insurance program, a model which was introduced two years later in British Columbia. By the mid 1950's similar Province-sponsored hospital insurance plans were in operation in four Provinces, in addition to those voluntary insurance programs which developed in the 1930's. At a Federal-Provincial Conference in 1955, the Federal Government proclaimed its willingness to provide financial support to provincially administered hospital plans. Impetus from this meeting led to the Hospital Diagnostic Services Act of 1958 which went into effect on July 1 of that year in the provinces of British Columbia, Alberta, Saskatchewan, Manitoba and Newfoundland. Ontario, New Brunswick, Nova Scotia and Prince Edward Island put the plan into effect on July 1, 1959, while Quebec, on January 1, 1961, was the last province to implement the program.

Under this system of government-sponsored hospital insurance, there was no limit on benefit days and admission was based on a loosely interpreted "medical necessity" as determined by the physician. The only costs borne by the individual were if he or she desired a semi-private or private room. Deductibles, or the concept of coinsurance, were discouraged because any costs paid by the individual were deducted from the 50% matching funds paid by the Canadian Federal Government to the provinces.

In a real sense, the passage of the Hospital Diagnostic Services Act in 1958, which was to be administered by the individual provinces, signalled the end of the private health insurance industry in Canada. Strangely, the insurance lobby did not seem to oppose what was tantamount to its ouster as a significant participant in the health insurance field. Blue Cross and some commercial companies remained in the business, however, by selling extended plans for private room coverage, ambulance services, private nurses, psychologists, etc.

The Socialist Government in Saskatchewan, in the forefront in the development of government hospital insurance, was again a motivating force in the development of medical care insurance. In 1960, medical care insurance for physicians' services was a big political issue in the province. The Socialists, advocating such a program, remained in office and secured a two-thirds majority in the legislature. The Saskatchewan Medical Association opposed such insurance and urged government involvement for only the poor and those over 65 years of age. Unmoved by this protest, the Saskatchewan government considered its election as a mandate for medical care insurance and argued that it would be a poor risk to cover just the poor and aged. On November 17, 1961, Medical Care, also known as the Saskatchewan

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Medical Care Insurance Act, became law which provided residents with a "free" comprehensive package of physicians' services. The protest by the medical profession continued after the legislation took effect as physicians were very much concerned that the universal compulsory government insurance plan would severely disrupt the physician-patient relationship. Many were fearful that a number of physicians would leave Saskatchewan and a Keep Our Doctors (KOD) Committee was formed in order to seek a compromise which would satisfy all parties. In May of 1962, physicians marched on the government and delivered the ultimatum that the Act be repealed or physicians' services would be withdrawn except for emergency care. The government did not budge and a strike began on July 1, 1962. Public feeling grew intense and even families were divided as to their loyalties toward the insurance plan and the physicians. Lord Taylor was called in from Great Britain on July 4 to begin to mediate what was to be known as the Saskatchewan Agreement. The agreement ended the 23-day strike, and Lord Taylor attributed his success to his ability in keeping the parties apart during the negotiations. Fortunately, no deaths attributable to the lack of medical care were recorded during the strike. Physicians were allowed to bill directly as a result of the Agreement, and the predicted mass exodus of physicians never occurred although some did leave the province.

In the summer of 1965, the Canadian Federal Government announced its willingness to assist the provinces in medical care insurance just as it had been doing since 1958 in hospital insurance. While the Canadian Medical Association had endorsed government-sponsored hospital insurance, it vigorously opposed government-sponsored medical care insurance. Physicians were concerned about retaining the right to practice outside the Plan and wanted guaranteed fee schedules without having to negotiate with the government. By 1969, all of the provinces had signed agreements with the Canadian Federal Government to offer a compulsory medical care insurance plan to their residents. If the provinces hadn't signed the agreement, their residents would have been forced to pay taxes anyway without receiving the medical care benefits. This "inducement" helped the provinces fall into line. The Medical Care Act went into effect on July 1, 1968, for British Columbia and Saskatchewan (although its individual provincial plan has been going since 1962). Alberta, Manitoba, Ontario, Nova Scotia and Newfoundland joined in 1969 while the Act was implemented in 1970 for Quebec and Prince Edward Island. New Brunswick, in 1971, was the last province to get the Act under way.

It is appropriate to view how the Canadian National Health Insurance system affects the consumer, the hospital and the physician.

## Consumer

From the consumer's point of view, he or she appears to be quite satisfied with the system—particularly in the provinces which do not impose a health tax or require the payment of an insurance premium. A Gallop Poll conducted in October of 1977 indicated that 88% of Canadians believed that they were receiving good medical care. About the only real complaint that the patients have is that the doctors don't spend enough time with them. The frustrations of dealing with a bureaucracy are not as great as one might imagine because NHI is administered by the provinces and not by the Canadian Federal Government. While it may appear to some that their health care is free, the individual is paying for it in various ways. For example, even in the five provinces (Saskatchewan, Manitoba, New Brunswick, Prince Edward Island and Newfoundland) which do not charge any premiums or health taxes, the consumer faces an increasingly onerous tax burden. Citizens of Canada are not allowed to use the standard income tax deductions which we have grown accustomed to in the United States. Canadians may not deduct home or office mortgage interest, sales or property taxes, and may not even claim the provincial tax in their federal return. With Proposition 13 in mind and the general preoccupation by citizens and politicians alike over taxes during the 1978 elections in America, one can easily envision how our country would react to having the Canadian tax system imposed on us.

In addition to the oppressive tax burden, three of the provinces help to finance their national health insurance through compulsory premiums (British Columbia, Alberta and Ontario) while the other two (Quebec and Nova Scotia) charge an income tax surcharge (of 1.5% for the individual and employer) and health service tax (8%). The premiums range from $90-$228 a year for a single person to $183.60-$456 for family coverage.

Inflation is currently running at 9%, about the same rate as unemployment in Canada. The construction industry has not been flourishing, partly due to the policy of not allowing tax deductions for mortgage interest. This restriction has not helped the savings and loan institutions, either. Lengths of stay rates in Canada are higher than in the United States partly because there is an acute shortage of nursing home beds. With little incentive to keep utilization down, hospitals are crowded and the waiting time for elective surgery is growing. Considering the Canadian tax burden and its currency which fluctuates between 83% and 87% of the American dollar, it is estimated that an American moving to Canada would need a 25% increase in income just to stay even.

As medical expenses increased in Canada since hospital and medical care insurance went into effect in 1958 and 1968, respectively, the federal government determined that it would have to cease granting 50% matching funds to the provinces. Four years ago it withdrew from its financial agreement with them and imposed on the provinces the entire burden for health expenditures. The federal government did extend tax credits, however, so that the individual provinces could keep a larger percentage of the federal income tax collected from them. This gesture was not equal to the 50% and forced the provinces to pare down medical expenses wherever possible. The new arrangement only served to bring physicians and hospitals under more control and contributed to the intensification of criticism against the medical profession.

### Hospitals

Generally speaking, the hospital physical plants in Canada are in fine condition. Unlike Great Britain, Canada encouraged a great deal of new hospital construction and the improvement of existing facilities before the implementation of its national health insurance program. Most Canadian hospitals do not have a problem with debts and borrowed capital unlike some of their American counterparts. Although there appears to be a surplus of beds in the immediate Toronto vicinity and other areas of the country, hospitals tend to be underbedded in Canada. The issue is subject to many different interpretations. Contributing to this situation is the acute shortage of nursing home beds. Canadian physicians seem to like their hospitals but are frustrated by an inability to move aged patients out of them into a more appropriate facility.

Originally most hospitals in Ontario were privately owned (Red Cross, United Church, Salvation Army, etc.), but now all are dependent financially on the provincial and federal government. Nursing homes have switched from small, privately owned organizations to larger homes, some of them of the chain variety.

Hospital costs are rising 8%-10% each year in Canada but the system only grants the institutions an increase of a maximum of 4.5% and some get as little as 0%. The government bases the percentage given on the degree of effort and success achieved by the hospitals in meeting various quotas and regulations. An immediate problem, of course, is to fill in the gap caused by increased costs of 8%-10% and the reimbursement of only up to 4.5%. Some institutions handle the problem through money raising efforts by their auxiliaries or foundations, but others not so fortunate to receive such help have to cut back on services. An operating room or some beds may have to be shut down or the hospital may reduce its nursing staff or pare down the number of registered nurses in favor of nurses' aides. In any event, even if the institutions are able to fill in the reimbursement gap, there still remains a tremendous problem to finance new or more sophisticated equipment, procedures and services.

As one might expect from the near crisis financial situation encountered by the hospitals, highly specialized services such as renal dialysis, coronary bypass, computerized axial tomography, etc., are highly controlled—some would say rationed. Simply said, there just are not funds available for new programs. One hospital administrator in Toronto complained that his institution was the only one in Canada which performed bone marrow transplants, and that was accomplished only through the considerable financial help of its foundation. Smaller hospitals are not so fortunate to be able to secure private financing, however, and are not flexible enough to offer new or improved services. A survey taken of hospital administrators indicated that there were many pressures caused by increased hospital costs, and although there were some benefits derived from cost restraints, in general the restraints have lowered morale and caused undue pressures on the health care system.

One problem Canadian hospitals do not experience with the same frequency as in those institutions south of the border is violence. The Director of Emergency Services of Ontario's largest hospital, a 1089 bed facility in Toronto, stated that he could not recall the last gunshot wound to come into his hospital. He said that it had been a month or two since the last knife wound had been observed. Most hospitals do not have any need for a security force to protect nurses and other staff. On the subject of emergency room services, it is interesting to note that Canada and the United States share the same problem of a growing demand for such services which could be performed in a physician's office.

One of the real pluses for Canadian hospitals and physicians when compared to their American counterparts is the malpractice situation. The 1089 bed institution referred to previously pays a yearly malpractice insurance premium of approximately $35,000 for up to $5 million coverage. An American hospital of comparable size can pay up to $1 million for the same protection.

Generally speaking, contingency fees are considered unethical in Canada although they are permitted (but seldom used) in the provinces of Saskatchewan and British Columbia. All physicians throughout Canada, pathologist and surgeon alike, pay $250 a year for malpractice insurance. The Canadian Medical Protective Association, which represents the medical profession, adheres almost totally to the hard rule of not settling cases out of court. A great majority of the cases are heard only by the judge, and very few go to a jury. Even if the plaintiff specifically requests a trial by jury, the chances are very slim that his or her request will be so honored. All of these factors have had a "chilling" effect on the number of malpractice actions brought against physicians and hospitals. With the number of new young lawyers in Canada escalating rapidly, it is very possible that the malpractice situation may be altered drastically in the ensuing years. Acceptance of the contingency fee concept and trial by jury might have quite an effect on their present rates and perhaps availability of insurance.

### Physicians

There is no question but that physicians in Canada feel a general sense of frustration. Since 1970, reports have indicated that the average wage earner has received an 11% increase each year while the physicians' increase has been held to 4% over that period. With inflation ranging between 7-9%, physicians have been under a financial strain. Many are working harder and seeing more patients in an attempt to keep up with inflation, but the result is less time spent with each patient. As alluded to previously, some physicians have found it necessary to cut back on their teaching time in order to accommodate additional appointments.

Physicians have become very displeased with the negotiated fee schedules which have been gradually reduced from 90% of the medical associations' fee schedule down to its present 70%. A doctor may charge his or her patient the regular fee, but the patient must be informed beforehand that the physician is not a participant in the government program. When the Medical Care Act took effect in 1968, the provincial medical associations urged their member physicians to opt out and not participate. But a great majority of physicians didn't want to opt out, and it was a case of the Chiefs going one way (opting out) and the Indians the other (participating). Clearly physicians and their medical organizations were not united in a strategy. Nationally, 86% of Canadian physicians have opted in and only 14% have opted out despite the urgings of the medical associations. Some physicians attribute these figures to history and tradition whereby their colleagues were accustomed to receiving monthly paychecks having participated in the Blue Plans and other insurance programs for many years.

Physician unity is hardly helped along by the mechanism utilized in distributing the meager 4% increase each year. After the negotiations are concluded between the provinces and each provincial medical association, it is the responsibility of the medical association to apportion the increase to the physicians. The medical associations survey various office overhead expenses, etc., in order to make the finest possible judgements, but it is easy to perceive the difficulties which surface as a result of this arrangement. Specialty groups are pitted against specialty group as everyone competes for a piece of the pie with no one able to keep up with the rate of inflation. As far as unity is concerned, it would probably be better for medicine if the government divided up the funds. In that way physicians could all vent their anger toward the provincial government instead of their medical association or a specific specialty group which received the highest increase.

Canada, a country of approximately 25,000 physicians, has been losing several hundred doctors a year since the early 1970's when physicians were first limited to the 4% increase. Some of them described the experience of attempting to keep up with inflation as running faster and faster on the treadmill and standing still economically. They are seeing more patients for less time in a vain attempt to stay even.

### General Observations

As one might expect when comparing Canada with its homogeneous population of approximately 28 million people and the United States with its heterogeneous population numbering more than 220 million, there are many interesting differences to observe between the two countries. There appears to be a philosophy and demonstrated willingness in Canada to sacrifice personal liberties for the betterment of society. For example, strict safety laws have been invoked which probably could not become law in the United States. Canada has a mandatory automobile seat belt law providing for a $75 fine for anyone found not wearing it. There are tough anti-smoking ordinances which exact heavy fines from violators. Drunken driving is dealt with severely with an automatic six-month suspension of the offender's license. The police have patrols (known to the public) which are authorized to stop a driver without cause in order to check for a drinking or seat belt violation. If a driver refuses to take a breathalyser test, he will forfeit his license for six months. It is interesting to note that the Ontario government, which has taken a leadership position in passing such laws, has been controlled by the Progressive Conservative Party for the past 35 years.

Critics of medical care in the United States will note the same type of problems in Canada. In 1976, the number of medical school graduates was frozen in some Canadian institutions and many have suggested that an over supply of physicians exists. The "maldistribution of physicians" problem is obviously not unique to the United States but is common to Canada and all other countries, too. With health care expenditures rising in Canada, there have been numerous discussions about exposing medical students to the economics of health care. Budget cutbacks in the medical schools seem to be having an adverse effect on the quality of teaching.

Medical research in Canada has been rather anemic of late and growing worse because of the cost constraints. It has been estimated that it spends on research about half as much on a per capita basis as does the United States. The Canadian government has sliced the funding for research each year and it appears that young people have been discouraged from going into academic or research careers.

Those physicians who join their provincial medical association must also join their national organization, the Canadian Medical Association. Some 85% - 90% of the physicians elect to join.

### Conclusion

At first glance, it appears that the Canadian Health Care System certainly is among the best, if not the best, medical care system in the world. Access, a problem of varying degree in all other countries, does not seem to present any difficulties to the Canadian people. Their hospitals generally are clean and bright facilities and, unlike Great Britain, were constructed in modern times. Direct health care costs to each citizen are minimal although their tax system leaves much to be desired.

One has a feeling, however, that the armor has just begun to crack. Hospitals cannot keep up with cost increases and nursing home beds are scarce. Funds allocated to research and new technology have been on the decline with no upturn expected. Hospital waiting lists are growing and time spent with the physician has lessened. Physicians have been "biting the bullet" financially since 1970 and it is claimed that some one percent of them are leaving Canada every year. The decline of the American dollar has been well publicized but the erosion of the Canadian dollar has been every bit as serious.

As medical expenses in Canada escalated, the Federal Government was forced to abandon its original 50% cost sharing plan with the provinces. Now the provinces are caught in the cost squeeze and they are looking for areas to cut back and lessen costs. This has meant and will continue to mean more regulations and cost constraints imposed on the providers of medical services, a situation which can only result in more unrest.

If lawyers' contingency fees become accepted throughout Canada and a malpractice insurance rate and availability crisis emerges as has occurred in the United States, the financial impact on their system could be disastrous.

Canadian politicians admit, although mostly in private, that physicians have been underpaid and that fees have been low. Increases, however, appear to be incompatible with government efforts to reduce costs. In view of the public demand for unlimited medical care with little or no incentive to keep utilization down, the government is in a quandary.

Clearly, physicians were not united when the government programs for hospital and medical care were implemented in 1958 and 1968. Medical association leaders urged their members to opt out of the system to increase their bargaining leverage, but they did not respond. There is no question but that the profession was fragmented, disjointed and unable to secure input into a system over which many have become deeply disenchanted. As Thomas Paine would have said, there were too many summer soldiers and sunshine patriots to effectively bring about adequate representation of the medical profession. Numerous Canadian physicians said over and over again that membership in one's medical association, both provincial and national, was of paramount importance.

Although there are many positive points to commend it, those who would impose the Canadian system on the United States had better look again.

# in Brief

## A summary of AMA, medical & health news

**Reductions in federal funding** for human services programs, biomedical research, and medical education in President Carter's proposed 1980 budget were criticized by the AMA. The President recommended $5.5 million less for the Maternal and Child Health Care program in fiscal year 1980 than in the current year's appropriation of $380.5 million. The AMA also pointed to a lack of federal support for such activities as the Voluntary Effort and PSROs, and to the continuing fraud and waste in federal programs. Key programs, which have already been badly eroded by inflation, must, at the very least, be maintained, the AMA said. The Association urged that more attention be paid to the spiraling cost of federal regulation and its inflationary effect on the budget.

**Drug distribution** should be governed by the physician's decision in all cases, after weighing all factors involved, including cost, said AMA Board Chairman Robert B. Hunter, MD, in commenting on a model state law proposed by HEW and FTC. The proposal would allow a pharmacist to substitute generic drugs for brand-name drugs unless the physician prohibits it. Dr. Hunter noted that, although the FDA monitors standards of drug strength, quality and purity and is developing a program to monitor bioavailability, there are no current controls to assure that all inert ingredients of generic drugs are exactly the same and to assure patient compliance with substitution. He pointed out that some formulators may wish to exceed FDA minimum standards and that physicians may wish to prescribe by brand to guarantee expected therapeutic results.

**In vitro fertilization** is ethical, the AMA told HEW's Ethics Advisory Board in a statement that also urged research on techniques "to assist those who wish to bear children but are presently unable to do so." At the 1978 Interim Meeting, the House adopted a resolution stating that "embryo transfer of ova fetilized by sperm involving husband and wife is ethical—with their informed consent of the various medical and legal componets"—and that "experimentation in the field of in vitro fertilization of human sperm and ova is ethical." The Ethics Advisory Board is holding hearings nationwide to determine whether federal financial support for such experimentation is warranted.

**Tenuate® Ⓒ**
**(diethylpropion hydrochloride NF)**

**Tenuate Dospan®**
**(diethylpropion hydrochloride NF) controlled-release**

**AVAILABLE ONLY ON PRESCRIPTION**
**Brief Summary**

**INDICATION:** Tenuate and Tenuate Dospan are indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use such as those described below.

**CONTRAINOICATIONS:** Advanced arteriosclerosis, hyperthyroidism, known hypersensitivity, or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states. Patients with a history of drug abuse. Ouring or within 14 days following the administration of monoamine oxidase inhibitors, (hypertensive crises may result).

**WARNINGS:** If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle, the patient should therefore be cautioned accordingly. *Drug Dependence.* Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of abuse should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with varying degrees of psychologic dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. *Use in Pregnancy:* Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential risks. *Use in Children.* Tenuate is not recommended for use in children under 12 years of age.

**PRECAUTIONS:** Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hypertension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of guanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.

**ADVERSE REACTIONS:** *Cardiovascular.* Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. *Central Nervous System.* Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache; rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. *Gastrointestinal:* Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic.* Urticaria, rash, ecchymosis, erythema. *Endocrine:* Impotence, changes in libido, gynecomastia, menstrual upset. *Hematopoietic System:* Bone marrow depression, agranulocytosis, leukopenia. *Miscellaneous:* A variety of miscellaneous adverse reactions has been reported by physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.

**DOSAGE AND ADMINISTRATION:** Tenuate (diethylpropion hydrochloride): One 25 mg. tablet three times daily, one hour before meals, and in midevening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release. One 75 mg taolet daily, swallowed whole, in midmorning. Tenuate is not recommended for use in children under 12 years of age.

**OVERDOSAGE:** Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phentolamine (Regitine®) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

Product Information as of April, 1976

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**References:** 1. Citations available on request—Medical Research Department, MERRELL RESEARCH CENTER, MERRELL-NATIONAL LABORATORIES, Cincinnati, Ohio 45215. 2. Hoekenga, M.T., O'Dillon, R.H., and Leyland, H.M. A Comprehensive Review of Oiethylpropion Hydrochloride. International Symposium on Central Mechanisms of Anorectic Drugs, Florence, Italy, Jan. 20-21, 1977.

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# AMA Health Issues and the 96th Congress

A number of health related initiatives failed to pass during the 95th Congress. Many of these issues are expected to reappear during the 96th Congress which began January 15, 1979.

However, there are changes in the complexion of the 96th Congress and continuing questions about the nation's economy that inject new sets of unknowns in the health legislation equation. How all of this will be resolved will not be known for some time.

This special edition of *Legislative Roundup* attempts to shed some light on the upcoming 96th Congress and the major health issues that may surface.

### Composition of the 96th Congress

The composition of the 96th Congress will be markedly different from that of the 95th Congress—and the change will affect the future of most federal health programs in a way which remains to be determined. While many new Congressional faces will appear on key health panels in 1979, their impact cannot be forecast accurately until Committee assignments are made next January.

Following is a review of the vacancies on the four major health Committees for the upcoming Congress:

- The Senate Finance Committee has lost four members—two Democrats and two Republicans. None of the four was a member of the Health Subcommittee. The two Republicans, however, Carl Curtis (R-Neb.) and Clifford Hansen (R-Wyo.), were the ranking Republican members of the Senate Committee, and their absence thrusts Senator Robert Dole (R-Kan.) into the minority leadership role in Finance.
- The Senate Human Resources Committee has lost only one member—Democrat William Hathaway of Maine, also a member of the Subcommittee on Health and Scientific Research. Of far more consequence to the health legislation within the Human Resources Committee, however, is the promotion of Health Subcommittee Chairman Edward Kennedy (D-Mass.) to the Chairmanship of the influential Senate Judiciary Committee. Whether Kennedy's involvement in that Committee will lessen his involvement in health matters remains to be seen; his recent hearings on the subject of national health insurance indicate he will continue to be a major force in health matters.
- The House Ways and Means Committee will be without eight of its members at the beginning of the 96th Congress, three of whom—Democrats Otis Pike (N.Y.), Omar Burleson (Tex.), and Martha Keys (Kan.)—were members of the Health Subcommittee. Nursing loses its main champion with the defeat of Keys. The main concern within the Ways and Means Health Subcommittee appears to be the future status of its Chairman, Rep. Dan Rostenkowski (D-Ill.). While rumors abound that Rostenkowski will not head the Subcommittee next year, he has not announced his decision whether to continue as head of this key health panel.
- The House Interstate and Foreign Commerce Committee has the most significant and potentially important changes in composition for the upcoming Congress. Nine members of the 43 member Committee are not returning in 1979, and the most significant departure, in health matters, remains that of the Chairman of the Subcommittee on Health and Environment, Paul Rogers (D-Fla.). Other absentees important to the future of health issues, however, include John Moss (D-Cal.), who chaired the Subcommittee on Oversight and Investigations, which under Moss' direction was often involved with matters involving organized medicine. Also missing is Rep. Joe Skubitz, a Kansas Republican who had served on the Health Subcommittee.

### Paul Rogers' Successor Still Unknown

Anytime a key member of Congress departs, Washington is awash with speculation as to the likely successor to the departed member's post. With the resignation of Paul Rogers (D-Fla.), the health community has been subject to a flood of rumors regarding a new Chairman for the important House Interstate and Foreign Commerce Health Subcommittee. While a final decision has not been reached regarding the final choice of a successor to Rogers, three Congressmen are now seen as the most likely candidates:

- David Satterfield (D-Va.), next in seniority to Rogers on the Health Subcommittee, would have succeeded Rogers without challenge were it not for his maverick image among Democrats. Essentially more conservative than other Democratic Subcommittee members, Satterfield is not considered the leading candidate but is still in competition for the appointment.

- Richardson Preyer (D-N.C.), a politician most like Rogers in political philosophy and demeanor, is next in line for the Subcommittee chair. Preyer, however, holds trust interest in Richardson-Merrill, and his drug company interest continues to act as a barrier to assumption of leadership of a Subcommittee with jurisdiction over drug legislation. Preyer has announced he will not preside over drug hearings in the Subcommittee, and is hoping that his financial ties will not prevent his accession to the Health Subcommittee chairmanship.
- Henry Waxman (D-Cal.), a less experienced Subcommittee member, is challenging Satterfield and Preyer, and has earned considerable backing from certain Commerce Committee members through his financial support of Democrats during the 1978 campaign. Waxman's main weakness is his relatively junior status in the Health Subcommittee.

While Satterfield, Preyer, and Waxman are the main candidates for Rogers' former post, other Congressmen, notably Rep. James Scheuer (D-N.Y.), are also potential choices. Hinging on the chairmanship is the Health Subcommittee's substantive direction, philosophical outlook, and of significance, the makeup of Subcommittee staff. The future of much health legislation hangs in the balance as the 96th Congress prepares to choose a successor to Paul Rogers.

### Carter to Cut Health Funds

As part of his efforts to control inflation, President Carter is proposing major cuts in the federal budget. Health programs could be particularly hard hit.

While the final decisions have not been made by the President, it is known that the Office of Management and Budget has suggested major cuts in funds such as health professions education and drug and alcohol abuse. Other areas may receive similar cuts or be held to "no growth" budgets.

Mental health programs are among the few that could receive more money. The Administration is also contemplating increased funds for programs that could curtail health care costs—such as health planning.

The administration may go to Congress with a recession plan. Such a plan would, if accepted by Congress, cut back funds already appropriated but not yet spent.

Although Congress is frequently more generous than the Administration, President Carter is confident that Congress will accept his lean proposal. Already Administration spokesmen are lobbying Congressmen and Senators, influential in the budget/appropriations process, seeking support for Carter's views.

### Federal Aid to Med Schools Expires

Programs of federal support for health professions education and manpower development will expire during the 96th Congress. Legislation revising and extending the authorities will certainly be of major concern to medicine and other health professions.

Congress has traditionally been generous to medical education, but fears of a physician surplus and concerns about geographic and specialty distribution of physicians may result in increased regulation and an end to the expansionist policies of the past.

The Administration is in the process of developing its own education and manpower proposals. Contemplated is a shift away from capitation funding to more targeted uses of federal funds to achieve goals of more even geographic and specialty distribution.

HEW Secretary Califano has already indicated that increased enrollments in medical schools are no longer necessary and that education funds will be tight in coming years. This may signal a lessened federal presence in medical education. However, a major reduction in federal spending will cause many schools to seek alternate sources of money. This could lead to tuition increases in many institutions.

It is not yet clear how issues of student funding will be handled. Increasing tuitions have caused many students to rely on federal scholarships and loan guarantee programs. There is pressure to increase the availability of loans and loan guarantees, but some in the Administration favor greater use of funds which would be tied to service obligations in medical shortage areas.

While there has been an expansion of minority enrollments in medical schools, a tight money situation could make it more difficult for some minority students to begin or continue their education. How to handle this problem has not been resolved.

President Carter's veto of the extension of nurse training programs assures that this issue will resurface early in the next Congress.

Legislative consideration of other health professions education and manpower issues is not expected until later in the 1st Session.

### Cost Containment Confusion

While hospital cost containment legislation was clearly the major health issue of the 95th Congress, it is currently a subject of considerable confusion as the 96th Congress approaches.

HEW Secretary Califano has recently indicated that the Administration would sponsor cost containment legislation in the 96th Congress. Other Administration sources, however, indicate that high level HEW officials are rethinking the Administration's cost containment strategy. Since none of the chairmen of the health subcommittees have to date shown any great interest in battling for cost controls again, HEW has been considering abandoning standby revenue controls in favor of voluntary wage and price guidelines. These voluntary controls would put additional pressure on the hospital industry's Voluntary Effort to cut spending.

Other methods of controlling hospital and physician costs generally are being planned by the Health Care Financing Administration (HCFA). HCFA plans to ask Congress to impose more regulations on hospitals and physicians including such initiatives as statewide negotiated Medicare physician fee schedules and limits on Medicare reimbursement for hospital-based physicians. Pursuant to alleged statutory authority in Section 223 of the Social Security Act, HCFA will also seek to limit reimbursement increases to hospitals for routine costs and other aspects of inpatient care to 11-12% next year.

Since the Voluntary Effort began, there has been a significant lessening in the rate of cost increases. Through August 1978, the rate of increase has been 12.9%, 3.0 percentage points below the 15.9% increase for the same period in 1977.

The presence of a successful VE forestalled Congressional cost containment action in the 95th Congress, and continued success could forestall further Congressional interest.

However, hospital inflation in October 1978 was higher than October 1977. If this trend were to continue, Congress may feel compelled to step in with a major regulatory program.

### Health Planning Again An Issue

Health planning legislation, extended for only a year by the 95th Congress, will again be a major issue for medicine in the 96th Congress.

The Administration considers successful passage of a health planning bill a major priority. Senators Kennedy and Schweiker have already announced their intention to introduce a bill similar to that passed by the Senate. Early action is expected there.

Changes in the health leadership in the House make quick action there less certain. Health planning organizations already plan an intensive program to move a bill through the House as quickly as possible.

Certificate of Need (CON) is sure to be a major issue in this area. The Senate could again pass a bill extending CON to all physicians' offices. It is not yet clear whether the House would accept that or support a more limited extension as it did in the 95th Congress.

### Future of Drug Law Reform Cloudy

The 96th Congress will see the Food and Drug Administration again pressing for complete rewrite of the Nation's drug laws. During the 95th Congress, extensive consideration was given to the Administration's "Drug Regulation Reform Act" by the Health Subcommittees of both the House Interstate and Foreign Commerce Committee and the Senate Human Resources Committee. However, the magnitude of the proposed changes to the existing law, along with opposition from consumer, manufacturing and medical groups insured that no new drug law would be enacted by the 95th Congress.

FDA and its parent HEW have targeted drug reform as a major priority for the 96th Congress. However, fast action in Congress is not expected. Senator Kennedy, the chief sponsor in the Senate, will be assuming the Chairmanship of the important Senate Judiciary Committee. While he will still be interested in the drug issue, his activities on the Judiciary Committee and his initiative for national health insurance could leave him significantly less time to push drug reform. In the House, it is still unclear which of the subcommittees of the House Interstate and Foreign Commerce Committee will be considering drug related matters. Paul Rogers, the past Chairman of the subcommittee was the principal sponsor and moving force behind the Administration's drug reform legislation in the House last year. With his retirement, it is unclear who will be the driving force behind the bill in the House. Furthermore, drugs may be shifted to a different subcommittee when Congress reconvenes in January.

Most knowledgeable observers of the drug regulatory process acknowledge that there can be significant improvements in the drug approval process. It is not, however, universally accepted that the entire drug law needs to be replaced.

Any Administration proposal to be introduced in the next Congress will attempt to do more than just improve the drug regulatory process. The FDA is expected again to attempt to shift the emphasis of its activities from solely determining safety and efficacy of drugs towards activities involving greater participation in the making of medical decisions and the regulation of medical practice. FDA is also expected to encourage provisions that would bring about increased competition in the marketplace for prescription drug products.

AMA has long supported FDA in its efforts to assure the marketing of only safe and effective drugs. To this end, AMA has developed amendments to the existing Food, Drug and Cosmetic Act designed to achieve this goal in as rapid a time as is consistent with the safety of patients. However, the AMA believes that FDA activities should be limited to the regulation of drugs and not to the regulation of the practice of medicine. Various provisions of the proposed Drug Regulation Act would have placed FDA in the direct role of limiting patient and physician access to certain drugs based upon diagnosis, approved dosages and the specialty training of the physician.

AMA believes that this shift of emphasis by FDA is both inappropriate and unnecessary and will continue to oppose such efforts by FDA to infringe upon the traditional role of the physician in making treatment decisions for individual patients.

### NHI Debate Heats Up Again

NHI activity during the 95th Congress was confined largely to a restatement of issues. Most of the major NHI legislation was submitted in the early weeks of the term and pressures for prompt enactment of a bill yielded to a cautious approach as the Administration and the Congress focused on problems of inflation and energy. The NHI debate continued, however, along lines of sharp conceptual differences.

In a new proposal outline, Kennedy-Labor forces are maintaining their momentum for a totally restructured health system. The proposal would create a role for insurance companies but assure federal domination over the delivery of health care. Carriers would be federally certified and regulated, operate on federally determined premium income, and administer claims at federally controlled institutional and professional charges. As in the original concept of the Kennedy-Corman Health Security Act, the principal source of funding would be a federal percentage levy of employer payroll and employee wages designated as "premium," and health care would be provided within a fixed budget of expenditure at national and local levels.

In contrast are those plans which would build on the present system of health care through private insurance and limit the government role to subsidizing premiums for those who could not otherwise afford to pay the premium. Other variations are public and private insurance plans that are targeted to a particular need, e.g., providing for maternal and child health care. In this regard, the Administration is again expected to push its own child health plan.

Despite extensive activities directed by HEW toward the development of an Administration NHI plan, no such plan has emerged. The guide to Administration thinking at the start of the 96th Congress is the President's statement of NHI principles which state, in part, that a plan would have to assure comprehensive health care coverage for all Americans, but that this goal would be achieved gradually in step-by-step legislation and within the constraint of no additional federal spending before fiscal 1983.

Disagreeing sharply with the Administration approach to phasing are those who insist on a legislative commitment to a full-scale NHI program now while allowing for phased implementation. Other advocates also emphasize that there is an urgent need to meet the health needs of millions of Americans who are without any insurance at all and millions more who are without adequate coverage.

Sen. Kennedy has held hearings across the country to drum up support for his new proposal. At the recent Democratic Party mini-convention, the Party reaffirmed its support for an NHI program. These actions will assure that NHI will be a major issue in the coming Congress. However, the country's economic woes and Carter's commitment to slow down inflation continue to be the wild cards that could forestall any quick action on NHI.

### Medicare/Medicaid Changes Possible

There was a significant amount of legislative activity concerning Medicare/Medicaid during the 95th Congress. This included Sen. Talmadge's S. 1470 and Congressman Rostenkowski's HR 13097 and HR 13817. However, none of these bills passed. The Administration and Congress will likely again concern themselves with many of the *same* Medicare/Medicaid issues in the 96th Congress. These issues include:

- Parity for psychiatric services;
- Repeal of Section 227 of the Social Security Act (which places a limit on the reimbursement of teaching physicians);
- Extension of Medicare payments for certain chiropractic and optometrist services;
- Medicare hospital reimbursement;
- Medicare physician assignment;
- Medicare statewide fee schedules for physician services;
- Changes in the Medicare definition of physician services;
- PSRO amendments providing for increased nonphysician participation in the development and implementation of peer review activities undertaken by PSROs; and
- Exempting PSROs from the information disclosure requirements of the Freedom of Information Act.

Much of this activity is generated by requests from various groups affected by Medicare/Medicaid policies. Every Congress sees a variety of bills designed to change these laws in ways that would be more favorable to one group or another. However, at this time it is difficult to say whether ranking members will decide to push for enactment of any of the proposals.

Another source of possible Congressional actions in this area may be legislative initiatives proposed by the Health Care Financing Administration (HCFA). HCFA is known to be considering changes in both reimbursement and administration of these programs, some of which may require Congressional action.

# Status Report on HMOs

*The following is a report prepared by the Council on Medical Service of the AMA and accepted by the AMA House of Delegates at its November-December Convention in 1978.*

## History

Health care costs have escalated over the decade from 1966 to 1976 with annual expenditures climbing from $42 billion to $137 billion. Hospital costs have shown a particularly sharp acceleration; such costs have increased nine-fold since 1950. Expenditures on health care have grown at an average annual rate of 11 percent. While a little over half of this growth is attributable to general inflation prices, this escalation rate is faster than for the rest of the economy. The health care share of the Gross National Product, now 8.6 percent, could, at present rates of growth, rise to 10 percent, or more, by 1980.

Some health economists and certain sectors of government contend that these increased expenditures will not result in additional health care benefits nor a more efficient health care delivery system, and are looking with renewed interest at the Health Maintenance Organization as an entity that can allegedly contain costs while delivering quality care in a more efficient manner. According to personnel at the Office of Health Maintenance Organizations, U.S. Department of Health, Education and Welfare, there currently* exist approximately 173 HMOs of which 68 are federally qualified and thus receive federal grants and loans, while the remainder are state certified. Of these 68 federally qualified HMOs, about 26% are located in the Western and Southwestern states, while about 32% are located in the Northeastern states with the remainder scattered throughout the Southern, Midwestern and Northwestern states.

While fairly recent legislation created the HMO acronym, the prototype HMOs really date back to such early prepaid group practices as the Ross-Loos Clinic in Los Angeles, established in the 1920s. Doctors Ross and Loos contracted with the city of Los Angeles to provide health care to certain city employees for a predetermined fee. In the early 1930s Doctor Sidney Garfield arranged a prepayment fee to provide health care to construction workers building an aqueduct from the Colorado River to Los Angeles.

The success of this plan prompted Edgar F. Kaiser to invite Doctor Garfield in 1938 to organize a similar plan for Kaiser construction workers. The nucleus of this last plan has of course grown into what has become the Kaiser-Permanente Medical Care program which today services some three million enrollees in six states.

By 1970, the Nixon Administration had identified containment of health care costs as a major priority. In evaluating possible solutions, the administration identified prepaid group practice as one mechanism they felt had a proven record in controlling costs. Paul Ellwood, M.D., a presidential health advisor, coined the phrase "Health Maintenance Organization" to describe prepaid group practice, and federal support was proposed to create a national network of HMOs. Accordingly, the Federal HMO Act (P.L. 93-222) was signed into law in 1973, granting experimental status to the federal HMO program and authorizing federal funds to be spent over a period of five years to establish and develop new HMOs.

According to this law, an HMO is an "organized, fiscally sound, legal entity, which provides and/or arranges for a comprehensive range of inpatient and outpatient health services to a voluntarily enrolled group of subscribers (who make or on whose behalf is made) prepaid, fixed and uniform payments to the HMO on a periodic basis." The Act had the force of putting the HMO at risk for providing the agreed upon services within the fiscal constraints of the agreed upon per capita revenue. It was theorized that this would create efficient management (administrative and fiscal) and tight utilization review of ambulatory and in-hospital services.

The 1973 Act required that an HMO provide directly or indirectly to its members a prescribed range of health services known as "basic health services," and that it offer the subscriber the opportunity to purchase additional but optional supplemental health services. In addition, the Act required the federally supported or approved HMOs to have an annual "open enrollment" period for everyone wishing to join regardless of health risk; and to establish the same per capita rate for all enrollees regardless of their health status (this is known as "community rating").

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*As of September 13, 1978.

It was the opinion of many involved with HMOs that the extensive benefit package requirement of the 1973 Act, coupled with open enrollment and community rating, resulted in per capita rates which were too expensive. It was argued that this put HMOs in an unfair position when competing with traditional health insurance plans and thus impeded the growth of the HMO movement. Thus it was claimed, the resulting high HMO premium created a great potential for failure because people would not want to make the increased out-of-pocket payment even though they might receive more benefits than under traditional health-insurance plans. As a result, Congress in 1976 passed amendments to the Act which loosened considerably the requirements for federal qualification of a health maintenance organization. The most controversial provision of the bill kept the open enrollment requirement only for HMOs that had been in existence for a period of five years or had 50,000 members. The Amendments deleted previously required preventive dental care for children but added to the required preventive services package. The 1976 Amendments also allowed a four year delay in the applicability of the community rating requirement. In addition the periods for use of loan and loan guarantee funds were increased. Finally, the amendments deleted the requirement to provide HMO members with the opportunity to contract for supplemental health services.

Even with the 1976 Amendments, there are still those in the HMO industry who feel that federal regulations remain too restrictive and that federal appropriations are not large enough. They argue that HMOs' record of effectiveness should move them out of the experimental realm and into a status of permanency, with federal appropriations and grant and loan programs sufficiently increased to support what they feel would be a viable national program. In response to this pressure both Houses of the 95th Congress (which ended in October 1978) introduced legislation which was favorable to the requests of the HMO proponents. Sen. Richard S. Schweiker introduced S. 2534 and Rep. Paul Rogers introduced H.R. 13655. The bill, as reported out of a Joint Conference Committee and passed by Congress, extended the authorized appropriations for grants and loans through fiscal year 1981. Initial development grants were increased from $1 million to $2 million. Also increased were annual HMO loans, which went from a cap of $1 million annually per HMO to $2 million annually per HMO. These loans cannot exceed $4.5 million per HMO through fiscal year 1981. For the first time a loan program (up to $2.5 million) is made available for the acquisition and construction of ambulatory care facilities and for the acquisition of equipment. Also established for the first time is an Intern Training Program for HMO administrators and medical directors. The amendments also require the Secretary of HEW to provide technical assistance to HMOs that are in various stages of development or operation.

### Types of HMOs

According to the 1973 HMO Act there are three modes of delivery of physician services through an HMO, whether it is federally qualified or state certified. The HMO can: (1) employ its own physicians on a salaried basis (staff model); (2) contract with one or more medical groups to provide care on a prepaid per capita basis (group model); or (3) contract with an Individual Practice Association whose physicians are reimbursed on fee for service basis.

*Staff Model:* Physicians involved in a staff model HMO work in a group practice clinic which is owned by the HMO. The physicians are paid a salary by the HMO; these revenues are derived from the monthly premium paid by the HMO's subscribers. Staff physicians may participate in a year-end bonus derived from any savings the HMO realizes in hospital, laboratory, x-ray and pharmacy utilization. This model usually has its own laboratory and x-ray facilities within its clinic, and may own its own hospital.

*Group Model:* Physicians involved in a group model HMO work in a group practice clinic which has entered into an agreement to provide physician services to the HMO subscribers. Generally speaking, a contract known as a Medical Service Agreement specifies the relationship between the HMO and the clinic. The physicians' group accepts a per member per month capitation as the principal form of payment for medical ancillary, hospital and clinic center costs and services, and assumes responsibility for the provision of medical services to the HMO subscribers. The per capita rate is paid to the clinic and the clinic may reimburse its physicians on a salaried or fee-for-service basis. The involved physicians may continue to treat fee-for-service non-HMO subscribers in order to meet federal qualification requirements. These physicians may similarly participate in a year-end bonus derived from any savings the HMO realizes in hospital days, laboratory, x-ray and pharmacy utilization. Usually the HMO will attempt to contract with a group clinic which has laboratory and x-ray facilities on site.

*Individual Practice Association (IPA):* An IPA is a legal entity which is organized and operated by physicians. It provides a mechanism for physicians to collectively enter into contractual arrangements with other parties, such as an HMO, to provide medical services from their offices to a defined population. Physicians join the IPA on an individual basis by signing a service agreement that among other things might prescribe the physician's agreement to: conduct the medical practice in accordance with the purposes and policies of the IPA; comply with peer review procedures established by the IPA; and accept a portion of the financial risk for delivering medical services within a fixed budget. It is important to understand that membership in an IPA does not limit a physician's practice to the treatment of patients covered under an IPA contract, or even require that a minimum percent of his practice be devoted to such patients.

Under this arrangement, the HMO receives a monthly premium from the subscriber group, and in turn pays the IPA on a monthly per capita basis for physician services. As the individual IPA physicians provide services to the HMO subscribers, they submit their claims to the IPA and are reimbursed on a fee-for-service basis, which is formulated on a prenegotiated usual, customary and reasonable schedule. The physicians usually agree to accept the IPA reimbursement as payment in full and not to bill the patient for any balance.

In most IPA arrangements, the physician agrees to assume some portion of the financial risk for delivering medical services. This risk percentage is generally 10-15% of his regular fee (which means that he agrees to accept 85-90% of his regular fee as payment in full). The portion of his regular fee not immediately distributed to him enters the IPA "risk" or "reserve" pool to provide a financial cushion for the IPA's operation and administrative costs. At year end, if the utilization has been within the projected parameters, the physician may receive the balance of up to 100% of his claims, after administrative obligations and reserve contingencies. The physicians may (depending upon the IPA-HMO agreements) share in any savings derived in hospital, laboratory, x-ray and pharmacy utilization.

### Federal Qualifications

Those HMOs which agree to offer the prescribed basic and supplemental benefit packages and to practice "open enrollment" and "community rating," as specified, are given status as a federally qualified HMO. This "federally qualified" designation provides HMOs with certain advantages, such as grants and loans, access to new markets via the dual choice option*, and a federal override of "restrictive" state laws.**

*Grants and Loans:* Those HMOs seeking federal qualification may receive grants totaling $2,275,000 for feasibility studies, planning activities and initial development. Those HMOs meeting the standards for qualification may receive direct loans to help cover operating deficits. These loans cannot exceed $2 million annually nor more than $4.5 million through fiscal year 1981. Additionally an HMO may receive up to $2.5 million for the acquisition and construction of ambulatory care facilities.

### State Certification

A Health Maintenance Organization may opt to be state certified rather than federally qualified. Generally, state certification is given by the State Commissioner of Insurance when assurance is made that the HMO application satisfies the standards of the state's Department of Insurance and Department of Health as set forth under the applicable law of incorporation. Currently 32 states have enacted specific HMO legislation.

### Claimed Benefits and Limitations

*Quality of Care:* According to many involved with HMOs the quality of care they provide is really determined solely by the degree to which a sound quality assurance program exists within the individual HMO. But DHEW has yet to define specific standards for HMO quality assurance, and a variety of quality assurance mechanisms are being or have been planned, developed, or implemented by federally qualified HMOs. This fact greatly concerns HMO critics who maintain that HMOs will be inclined to "skimp" on their quality of care by "undertreating" patient needs.

The "skimping" argument is answered by HMO proponents who cite Section 1301(c) (8) of the HMO Act that requires qualified HMOs to conduct ongoing quality assurance programs. But HMO critics quickly point to *A Report to the Congress,* released in June of 1978 by the United States General Accounting Office, which surveyed several federally qualified HMOs and their compliance with the qualification regulations. With regard to quality assurance the report concluded:

> ". . . HEW, and therefore HMOs, still lack specific, definitive standards for quality assurance programs. As a result, HMOs have designed programs which include a variety of features. To become qualified, an HMO must have a planned

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*Dual Choice Option: Any employer who is required to pay his employees the minimum wage, who employs an average of 25 employees and who has a health benefit plan that is offered to eligible employees, is now required to offer employees the opportunity to select a qualified HMO plan as an alternative to their existing health insurance plan if petitioned by a federally qualified HMO.

**Override of State Laws: The HMO Act supersedes several provisions of state laws which regulate the development of HMOs, such as medical society approval; participation in service delivery by a certain percentage of physicians; representation by physicians on policy and decision bodies; and requirements that the legal entity meet requirements designed for insurers with respect to reserves.

> quality assurance program; however, many of the HMOs we evaluated had not fully implemented their programs at the outset of operations. As of early 1978, HEW had not made site visits to assess HMO's compliance with quality assurance requirements and had not finalized procedures for assessing compliance."

A March 28, 1978 study released by Inter Study (A Minneapolis based HMO study group headed by Doctor Paul Ellwood) for the National Chamber Foundation stated that: "although there are no generally accepted measures of quality, evidence suggests that HMOs provide equal or higher quality care than the traditional system."

Other studies show no difference between the amount of treatment and preventive care HMO members and fee-for-service patients receive, except for hospitalization. Some of these studies indicate HMO patients do go outside of the group for 10% or more of their medical care, which critics cite as suggesting some dissatisfaction.

*Cost Effectiveness:* Many HMO spokesmen maintain that HMOs are cost effective because of decreased hospital utilization by members, both in terms of lower admission rates and shorter lengths of stay. Critics of the HMO program, however, suggest that lower hospital utilization in an HMO derives not so much from efficiency of practice, as it does from actively seeking to enroll a young, healthy population of subscribers, and also question where appropriate utilization ends and *underutilization* begins.

Claims of HMO cost savings are usually calculated on a basis of hospital days used per 1000 members. During the period February 1977 to August 1977, a census of HMOs was conducted by the Group Health Association of America. This census determined that overall, the number of hospital days/1000 members (in the 165 HMOs then in existence) was 458, compared to 800-1000 for traditional-type insurance plans. These lower HMO hospitalization rates are due primarily to lower admission rates rather than lower lengths of stay, according to a June 1978 article in the *New England Journal of Medicine.*

In a report to the Congress, published in June 1978 by the United States General Accounting Office, it is suggested that lower hospitalization days/1000 HMO members may be attributed to population selection. Qualified HMOs are supposed to enroll everyone, regardless of health status, via the open enrollment requirement; but because this requirement may be waived for a period of five years, it is implied that HMOs only market coverage to young, healthy subscribers, who utilize hospitals less.

The March 1978 National Chamber Foundation Report compared utilization based on inpatient days of HMOs and Blue Cross regular membership in seven states having the largest number of HMOs. The Report calculated a savings of 782,000 days of care, for a sample of 67 HMOs, as compared to the estimated hospital utilization rate expected under a Blue Cross plan. This report maintains that the lower HMO hospitalization rates stem both from fewer admissions and shorter lengths of stay.

### Future Activities

To evaluate these claimed benefits and limitations, the Council on Medical Service has initiated an objective information gathering program on the operation of different types of HMOs. Through a series of site visits to operating examples of each HMO model—staff, group and IPA—the Council will assess the impact of these programs on quality, availability, and costs of medical care as it is perceived by involved and non-involved physicians, patients, and administrators. The findings of this assessment will be conveyed to the House in future reports, so as to assist the membership in making informed judgements on these practice modes.

The Council is convinced that the most valid information on the efficacy of HMOs will result from allowing such program to compete with other delivery and financing mechanisms in a health care market free of artificial restraints or on advantages to any one approach, and strongly supports the past emphasis placed by the House of Delegates on such free market competition.

To reinforce that emphasis, the Council *recommends that the House of Delegates reaffirm its support of the concept of neutral public policy and fair market competition among all systems of health care delivery.*

# *Month In Washington*

Here's how physicians' fees compared with other price changes in 1978.

The annualized rate of growth of physicians' service prices for 1978 as a whole (8.0 percent) was less rapid than either the all items (9.1 percent) or the all services (9.7 percent) indices of the consumer price index.

For 1978, the 8 percent annualized rate of growth of physicians' service prices was lower than the rate of growth for the medical care index (8.2 percent), or the medical care services index (8.6 percent). The physicians' service rate (8.0 percent) exceeded the rate of increase for prescription drugs (7.3 percent), dentists' services (6.6 percent), and medical care commodities (6.8 percent).

Published Consumer Price Index data are available for only the first nine months of calendar year 1978. However, data are complete for the federal fiscal year, which runs from October through September. The figures presented here are for the federal fiscal year, 1978.

For fiscal year (FY) 1978, physicians' fees rose at a lower rate than the "all items" index, or the "all services" index (7.7 percent versus 8.0 percent and 8.7 percent, respectively.)

For FY 1978, physicians' fees rose at about the same rate as the medical care index (7.7 percent for physicians' fees and 7.6 percent for medical care). Also, physicians' fees rose more rapidly than dentists' fees (6.1 percent) and prescription drugs (7.3 percent) and not as rapidly as hospital semi-private room charges (9.9 percent).

The annual rate of growth of physicians' fees fell in FY 1978 to 7.7 percent from the FY 1977 rate of 8.8 percent. This represents a 12.5 percent decrease in the rate of growth.

Physicians' fees rose at a greater rate than prices in the economy as a whole in FY 1977 and at a lower rate than prices in the economy as a whole in FY 1978.

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*Prepared by the Washington, D.C.*
*Office of the American Medical Association*

The Carter Administration appears to be leaning toward a broad national health insurance proposal that features establishment of a federal insurance program—healthcare—to stand alongside existing private plans.

While commitment is not final, a "National Health Plan" (NHP) has been submitted by the Health, Education and Welfare Department to the White House for approval.

President Carter has many questions and reservations about the approach and he has not made up his mind on crucial issues such as whether Congress should be asked to approve the plan as a complete package.

The NHP is the one that high level policy discussions are centering on now. It is a more sweeping national health insurance plan (NHI) than expected. There had been an inclination at HEW for a long time to adopt much more modest variations of NHI in response to Carter's frugal government campaign. The program finally settled upon at HEW reflects a significant bow to the pressures of organized labor and Senator Edward Kennedy (D-Mass.) for a comprehensive NHI.

The Administration won't be submitting its final legislative proposal to Congress for several months. There is a possibility the plan might be worked over and changed drastically from its present form. Even HEW in its report to Carter emphasized the tentative nature of the plan's provisions.

Following is a description of the NHP proposal in which much of the language is that of the HEW Department.

The universal, mandatory national health insurance program would provide the same standard of insurance protection for all Americans through either the public or private sector. The tentative plan would maintain a pluralistic system of health services financing, yet assure that all Americans would have insurance coverage.

The plan would establish a federal insurance program—healthcare—under which people would be covered by either NHP or by private insurance plans meeting federal standards. Employers would be required to purchase coverage for employees from

NHP or private plans would be covered for the same standard benefit package and treated equally by health service providers, because all insurance plans would reimburse providers at the same rates. Comparability between public and private plans in benefits and rates of payment to providers would be achieved through standards governing benefits offered by private plans and their rates of payment to hospitals, physicians and other health service providers. Providers would have no reason to distinguish between persons enrolled in different insurance plans because all financial transactions would occur between providers and insurance plans, rather than providers and patients; and all plans would pay the same amount for a given service.

The benefit package for all plans would include hospital, physician, outpatient, laboratory and X-ray services, a complete prevention package as well as limited coverage of mental health, alcoholism and drug abuse services and outpatient drugs.

Under one set of provisions, the HEW Secretary working with a provider rate negotiation board would annually set payment rates for all services covered under the plans at levels calculated to meet a spending target established by the Congress. Hospitals would be reimbursed prospectively.

Under an alternative set of provisions, fee schedules would be established for physicians and expense limits for hospitals. This approach would be more evolutionary and fee schedules and expense limits could be set at the state or local level initially.

The National Health Plan or NHP system would be financed through a combination of premiums, current medicare payroll tax payments and federal general revenues.

A federal reinsurance fund would serve to equalize the cost of exceptionally high expenses among private insurance plans and NHP. The reinsurance fund would assume responsibility for any individual expenditure in excess of $50,000. Reinsurance would be financed through federal general revenues.

* * * *

A health advisory group of the Republican National Committee has rejected any program of federally-financed, federally-administered national health insurance, calling instead for "appropriate steps" to provide for the uncovered poor and those threatened by catastrophic expenses.

The report was filed by the Health Subcommittee of the GOP Committee's Advisory Council on Human Concerns. Heading the panel was former Pennsylvania Senator Hugh Scott.

The efforts of the Carter Administration and the Kennedy-Labor wing to impose a sweeping NHI program were assailed in the Republican Committee's report, "A Statement on Health Policy."

Some Democratic members of Congress have proposed a $300 billion NHI, noted the document. "At a time when a workable national health policy is essential all we hear from the President is vicious attacks on our medical professionals and a set of 10 principles for national health insurance which considers the details of cost and coverage without addressing the question of why a totally federalized national health insurance program is needed at all." asserted the GOP panel.

Recommended was "a system which would build on and strengthen the private insurance protections which now cover more than 80 percent of the population rather than tearing that down."

President Carter has told Congress that it must act this year on the Administration's hospital cost containment proposal.

In his State of the Union Speech, Carter said, "There will be no clearer test of the commitment of this Congress to the anti-inflation fight than the legislation I will submit again this year to hold down inflation in hospital care."

The Administration has decided to abandon its original goal of a mandatory federal ceiling on hospital expenditure increases in favor of a fall-back position in which controls would be imposed only if the voluntary effort to restrain increases fails to keep expenditures within certain limits.

The plan faces a tough fight in Congress where the general mood is in opposition to controls, even standby controls. The Senate approved a watered-down version of the Administration plan in the last few days of the previous Congress, but the House refused to act.

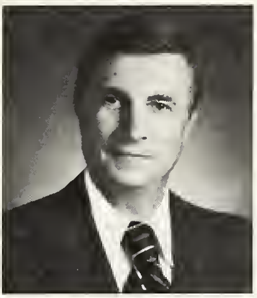
HEW Secretary Califano gave the picture a new twist with a request that hospitals next year limit their expenditure increase to 9.7 percent.

The HEW proposed guideline was attacked immediately as "totally unrealistic and based on assumptions which we believe are unreasonable," by the Federation of American Hospitals.

The American Hospital Association quickly joined the attack with the statement that a 9.7 percent cap would "absolutely endanger our ability to take care of patients." "Now that we (Voluntary Effort program) have mounted an obviously successful program—it is being ignored with the unfortunate introduction of a new mechanism," AHA president Alexander McMahon said.

# The President's Page

## Status Report on Relations with the Connecticut Hospital Association



The past history of CSMS—CHA relations is one of equal parts of antagonism, mistrust, misunderstanding and faulty communication. We disagreed often, publicly and bitterly on legislation, regulation, national health insurance, the respective place of physicians and hospital administrators in the scheme of things and on other matters that I am too young to know of. As regulation of the health industry increased, on given occasions the hospitals came under the gun and physicians felt it was what they deserved. In the reverse situation the feeling was reciprocated from the hospital side.

Some on each side, however, began to see that there were hostile forces out to hang us separately or together as Gordon McWilliams of the Middlesex Memorial Hospital so succinctly put it. The activities of the Connecticut Commission on Hospitals and Health Care were so inimical to the patients and the two groups, that CHA and CSMS were almost forced together. Perhaps one of the most important results of Mr. Bernard Forand's activities, unintentional I am sure, has been to bring the two professional groups together. Dr. Isidore Friedberg, my good and wise predecessor, began joint meetings of the leaderships and kindly asked and encouraged me to participate. We addressed cost containment ventures, joint activities in dealing with new technology to assure proper information to administrative and legislative decision makers to balance what seemed to us often blindly cost saving oriented actions, and many other matters of interest to one, the other or both groups. The most important activity was the building of personal relationships between us. Unknown to us, Dr. Sammons of the AMA and Mr. McMahon of the AHA were building similar bridges.

When the hospitals felt constrained to litigate the unfair decisions of the Commission on their budgets, the CSMS did not interfere though we might have had some variances of viewpoint of small degree. When we were faced with extension of Certificate of Need to our offices, CHA with fairly strong feelings on the matter, informed us it would take no position and did not, either covertly or overtly. By the time Informed Consent loomed as a severe problem mainly for the hospitals but only a little less for the physicians, it had become logical to work together. And we did, during many months of tripartite negotiations with the state health department. A joint committee to deal with technology assessment has just been launched and we look for solid accomplishments from it in the future. Several months ago, when the CHHC proposed regulations to control the number of patients seen each year by our hospitals, it had become natural for CHA leadership to ask if we could help. I felt there was no question of the severity of the danger for hospitals but also that patients and therefore my physicians were deeply concerned as well. So it seemed indicated for me to testify against the proposed regulations. I was assured we really had no chance but the witnesses surely gave it a good try. At this writing, the proposals have disappeared and while there never can be relaxation of our attention since resurrection is always possible, I think we may take a certain small pride in the effort so far. I learned only afterward that this was the first time in memory that the President of the CSMS had testified supporting the CHA on a matter primarily of interest to CHA.

I write this page from Washington where I am attending the AHA's House of Delegates as a guest of the CHA. It is the first time any state hospital association has invited the president of its medical society to join it. And I have accompanied teams of CHA people in their visits of Connecticut's congressional delegation. I have been made more than welcome, have learned a great deal and have been told I was of some use, a statement which I think may be less than deserved. The CSMS has not had a system of yearly visitation to congressmen and senators for some years and it is something to consider emulating.

You may think all is sweetness and light. It is not and should not be. There have to be times when the interests of the two groups are divergent. Hopefully, we will know each other well enough to agree to disagree and do so in a gentlemanly fashion and do each other no unnecessary hurt or harm. Our relationship has to be of equals. There will be no sellouts in either direction. Hopefully, we will do good not only for our two constituencies but for the people of this state as well. They could be well served by improvement in the quality of input from our two organizations of health professionals to regulators and elected officials. I personally believe far more could be possible.

Jerome K. Freedman, M.D.
*President*

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# Reflections from the Dean's Office

## To Market, to Market

ROBERT U. MASSEY, M.D.

In the past few years, those of us who are responsible for medical schools, hospitals, and clinics have learned to use the language of managers, the concepts of businessmen, and the ways of the marketplace. We can even read balance sheets and talk of sources of revenue, fund balances, and capital expenditures. Although the idea of profit is not admissible, we have occasionally used the expression "bottom line," and have pretended to imply a modified meaning.

But marketing is another matter. Even though Codman spoke of the "product of the hospital" 65 years ago,[1] marketing that product was never conformable with our professional upbringing. Marketing, in our minds, had to do with advertising, and that meant trying to create a need for something which was intended to be used only when the need was already present. If marketing was to make our profession and its institutions look more attractive or be more useful, then *marketing* itself was a bad marketing term.

Webster's Dictionary defines marketing as "the act or business of buying or selling in the market," or "to expose for sale." Hospitals and clinics are not hidden; they are often in handsome buildings in prominent locations. Newspapers frequently mention their names, and people like to feel proud of their community hospitals. They do not resist exposure, but they rarely employ an assistant director in charge of marketing.

In these times when the costs of medical care are rising faster than inflation, and the physician, of whom Chaucer wrote

> "For gold in phisik is a cordial,
> Therefore he lovede gold in special,"

is blamed for causing most of the trouble, his and the hospital's efforts to market their product are not likely to be viewed as being in the public's interest.

Yet if we believe that the market works better than government regulations to establish prices and to distribute scarce resources, we shall need to accept some concept which is like marketing. There are many kinds of markets between the oriental bazaar and a department store in Moscow; most market conditions are well within those extremes. We are living now with excessive and increasing governmental bureaucratic regulation; we might turn with a sense of freedom to the confusion of the marketplace, and be exhilarated by the dust and noise of the *agora*. But we need to be cautious; competition could waste our resources.

Marketing as a management term has been defined in many ways, and for hospitals it might include everything from patient attitude surveys to lounges for visiting physicians. It should include patient education in how not to use medical and hospital services, as well as physician education in how to use the hospital on the weekends. It should mean being less arrogant and more accommodating, and having helpful attendants in the parking lot. It should mean waiting no more than five minutes in the clinic, and *almost* never losing a chart. It should mean intelligible bills.

In Europe there are stirrings on the right and on the left away from government control toward more social and economic freedom. Our own feverish penchant for regulation of everything may be about to induce a healthy reaction. Suzanne Berger, a political scientist at the Massachusetts Institute of Technology, has described two means for unloading the state: "political decentralization, on the one side, and a transfer of decisions out of politics and into the market, on the other."[2]

Marketing may have to be tamed if we are to use it to make headway against the tyranny of a controlling government. Competition managed by ourselves and discipline self-imposed in the public interest could be the middle way.

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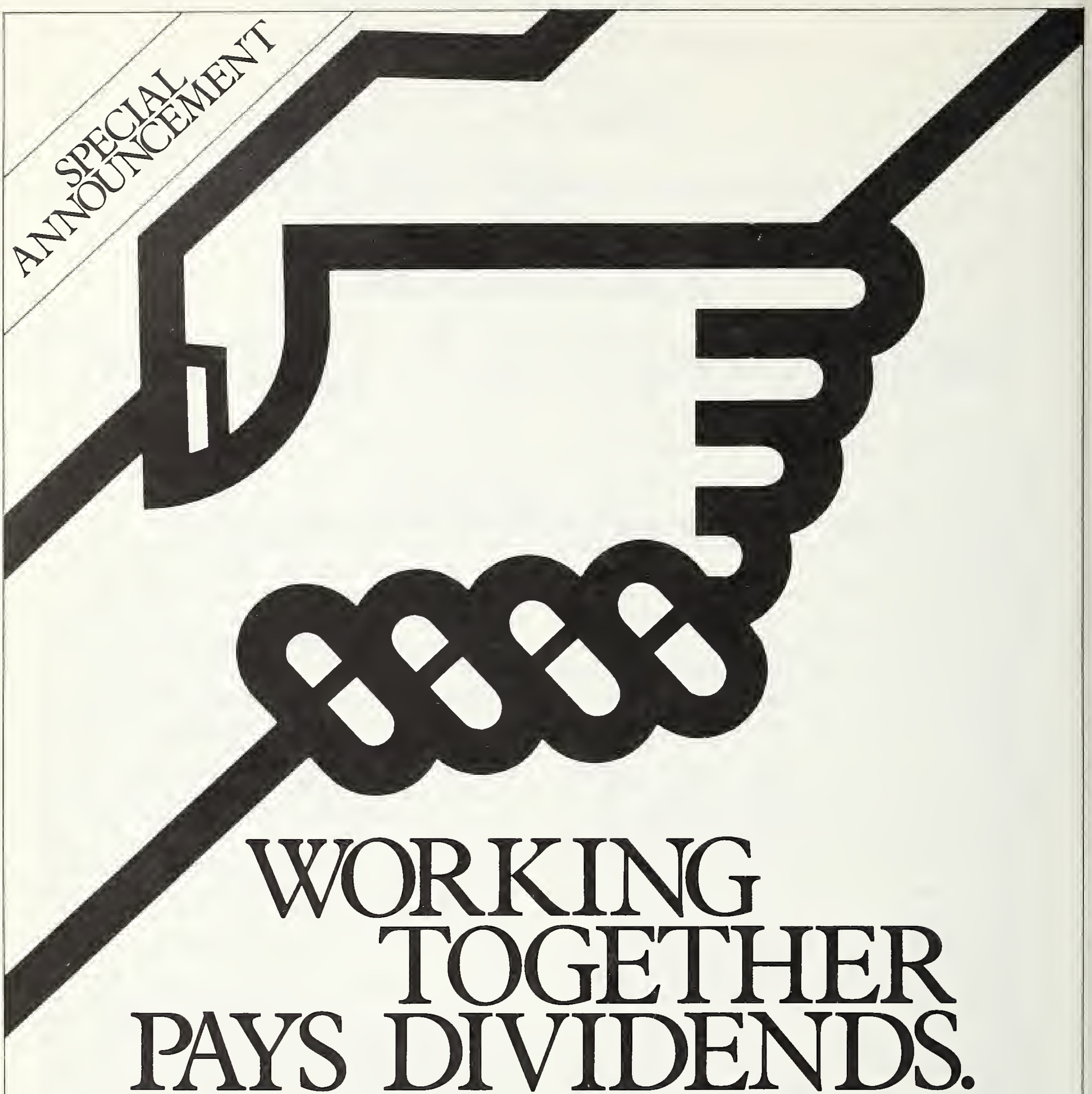

SPECIAL ANNOUNCEMENT

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# Medical Law and the Health Care Process

JOSEPH M. HEALEY, J.D.

Many physicians are convinced that the law is playing an excessive role in regulating the health care process. Their comments are part of a general concern in our society that we are experiencing a period of over-legalization and over-regulation. Both *Time* and *Newsweek* have devoted cover stories to this phenomenon. The evidence supports both the general concern and its application to regulation of the health care process.

An individual practicing medicine or surgery in the Connecticut of the 1860's was found by Ordronaux to encounter little regulation.[1] There was no licensure system, minimal reporting requirements (births, deaths and pestilential diseases) and limited guidelines for the performance of dissection and post mortem examinations. In contrast, the contemporary practitioner is faced with an imposing array of regulations. A glance at the current index of *Connecticut General Laws*, the collected state statutes, reveals that there are more than 275 references and cross-references to statutes regulating the practice of medicine and surgery. This number does not include the additional references to other health care providers or to health care facilities. The volume of regulations is staggering and its impact upon the health care process is at best, an uncertainty.

The theme of excessive legalization and regulation is present in a wide variety of settings in our society from baseball to the sale of consumer goods, from school financing and administration to the rights of the snail darter. Increasing reliance upon the formal mechanisms of our legal system to replace informal mechanisms of conflict resolution in our society is a sad commentary on the viability of those informal mechanisms. What is most disturbing is that reliance upon the legal system can obscure the legitimate justifications for legal involvement in regulating the activity at issue. Such appears to be the case with the health care process.

Legal regulation of the health care process has its primary roots in the police power, the power "to enact and enforce laws to protect and promote the health, safety, morals, order, peace, comfort and general welfare of the people."[2] This power is an inherent power of a sovereign government which is derived from its very nature as a government. The fifty states are the primary contexts in which this power exists and is exercised. The federal government is a government of delegated powers and does not possess this power in its broadest sense. The police power is the source of such health care regulations as medical licensure and compulsory immunization. It is not difficult to understand the fundamental importance of this power, or regulations based on its exercise.

Furthermore, the law has always played a role in adjudicating conflicts involving the rights and duties of people in society. By applying general principles of the civil law (e.g. contracts and torts) and the criminal law (e.g. prohibition against homicide) to interpersonal relationships in general, and to the physician-patient relationship specifically, the law has assumed its logical role in the just resolution of disputes within society. While one might disagree with specific responses of the legal system to specific problems, it is not difficult to understand the importance of this role.

However, the volume and breadth of regulation which we are experiencing now is not often clearly grounded in either of these major sources and indeed may be more an expression of societal frustration than of an appropriate exercise of legal regulation. The invocation of the interstate commerce clause[3] as justification for occupational health and safety legislation and federal control of genetic research raises serious questions in that regard. A second serious problem involves the extent to which the receipt of federal funds can be conditioned upon compliance with broad policy goals. The North Carolina experience with certificate of need legislation is instructive in this regard.

My concern, quite simply, is that the frustration of health care providers with excessive regulation of the health care process might lead them to proclaim that the health care process is or ought to be outside the scope of any legal regulation. This over-reaction would be based upon a failure to understand that there are legitimate goals for such regulations and that the major question is determining how best to achieve these goals. I don't, of course, know the answers to that question. But I do know that unless law and medicine face the problem in a cooperative spirit, there will be not resolution but continuation of the inter-professional hostility and antagonisms which have clouded our relationship during the last decade. A major goal of this column and of those to come is to encourage the development of that cooperative spirit.

## REFERENCES

1. Ordronaux, J. *The Jurisprudence of Medicine* (1869)
2. Grad, F. *Public Health Law Manual* (1975)
3. *U.S. Constitution* Art. I, Section 8, cl. 3.

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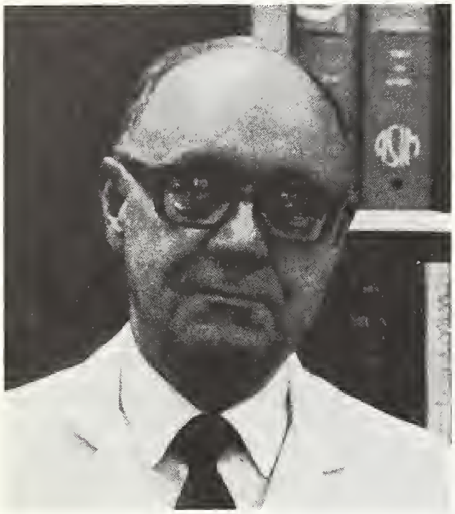
JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

# “THE PHYSICIAN IS A DECISION MAKER, AND ALMOST EVERY DECISION HE MAKES COSTS OR SAVES MONEY.”

*—Dr. William Felts, Past President,*
*American Society of Internal Medicine*



More and more physicians today are beginning to realize the extent of the economic influence they have, and are finding ways of holding costs down.

A number of studies show that the more physicians *know* about costs, the more they try to *reduce* them.* And this reduction can be done without reducing the quality of care to the patient.

How are they doing this? As a start they have become thoroughly familiar with the costs they incur on behalf of their patients. They know how much an X-ray costs, how much their hospital charges for routine lab tests. They’re requesting copies of patients’ hospital bills. And asking their hospitals to print the charges for diagnostic tests right on the order sheet.

What else are physicians doing? Minimizing their patients’ hospital stays, whenever possible. Reevaluating routine admissions procedures. Questioning the real need of the diagnostic tests they order for their patients. Avoiding duplicate testing. Trying to discourage their patients’ demands for unnecessary medication, treatment or hospitalization. Compiling daily logs of their medical decisions and what they cost. And more.

More physicians today realize what a tough problem we’re all faced with. They know this is a challenge for medicine. And that physicians are in the best position to deal with and solve the problem.

**PATIENT CARE Magazine—Outlook 1977, “Face-Off: Cost Containment vs. Chaos,” January 1, 1977.*

*Lyle CB, et al. “Practice habits in a group of eight internists,” ANNALS OF INTERNAL MEDICINE 84 (May 1976), 594-601.*

*Schroeder SA, et al. “Use of laboratory tests and pharmaceuticals: variation among physicians and effect of cost audit on subsequent use,” JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 225 (Aug. 20, 1973), 969-73.*

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**Connecticut Medicine**

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# EDITORIALS

## Scoliosis Screening: Preserving Spinal Integrity and the Health Care Dollar through Prevention

Avoiding the crippling effects of a progressive scoliosis through timely treatment has been a long term goal of the orthopedic community dating from the literal translation of the specialty name chosen by Nicholas Andre over two hundred years ago and before. In the past generation Risser, Cobb, and Harrington to name a few have been responsible for improving fusion techniques in those patients with curves severe enough to require treatment. The treatment of less severe curves with bracing only, has been shown to be practical over the past fifteen years through the works of Blount and Moe. This set the stage for the development of preventive programs as described in Dr. Renshaw's article in this issue of *Connecticut Medicine*. The results are well documented. In Delaware a state-wide program of screening has been in place for fifteen years and in Minnesota for five years. In the year 1975 only one patient in Delaware and three patients in Minnesota required fusion surgery. By contrast over seventy fusion operations were carried out in Connecticut in 1975 with their associated economic, physical and emotional toll.

Those patients with a private physician who is utilized would rarely get into such trouble. However, present patterns of care do not meet this standard. We are dealing with a population that frequently uses the Emergency Room as its private physician and an age group that is generally self-conscious in disrobing so that even parents rarely see an exposed back. Recognizing these problems, the House of Delegates of the Connecticut State Medical Society passed a resolution introduced by Dr. Gage supporting the development of a Scoliosis Screening Program at its April, 1978 meeting. Newington Children's Hospital and Drs. Renshaw and Gage are to be commended for already implementing the voluntary programs in June, 1978 with a session for interested physicians and more recently with regional programs for school nurses and physical educators on the practical aspects of screening in the local school. I can only wish them complete success so that Connecticut can also boast of the essential elimination of severe scoliosis.

Norman A. Zlotsky, M.D.

## Laetrile—Again and Yet

The Supreme Court has finally agreed (January 22) to review a ruling by a federal appellate court that limits the Food and Drug Administration's authority to prohibit the use of Laetrile as an anti-cancer drug.

Quite by accident, its decision occurs at the time when the case of Chad Green, a 3-year old child, suffering from leukemia, is being litigated in Massachusetts courts—the issue being a dispute between the State and his parents as to the treatment of their child with chemotherapy as advised by physicians, with prohibition of the use of Laetrile as desired by the parents. The condition of the child is not terminal. With chemotherapy it is estimated that up to 90% being treated may survive up to five years, and 50% of them may be disease-free at seven years. Without chemotherapy, the disease can kill within four months.

There are several important issues of interest to physicians, but I will discuss only one: the role of the medical profession in the public's desire to use

Laetrile and drugs and techniques considered quackery by the medical profession. More than 14 states and at least one federal appellate court have legalized the use of Laetrile. This is unprecedented in that no therapeutic agent has ever been introduced by legislative action without a clinical, scientific evaluation. Between 50,000 and 100,000 Americans are said to have taken Laetrile last year. Here the FTC has legitimate authority to protect the public. While we physicians may sincerely believe we have the public's interest in our efforts against quackery, increasingly the public believes we are protecting our own pocketbooks.

In the May 1977 issue of *The New England Journal of Medicine,* Dr. Franz Ingelfinger, himself a cancer patient, while agreeing that Laetrile is not only worthless, and potentially lethal, would legalize its use under certain conditions. For mentally competent adults, I agree.

So what is the role of the medical profession? At a recent convention of the AMA, while there was general agreement that Laetrile is worthless and even dangerous, discussion was heated and emotional. One influential delegate stated on the floor of the House that it was immoral for a physician and the profession to advocate permitting its use. It seems to me that the medical profession should be available as experts to testify and render scientific opinion and evidence when requested. We should advocate and sponsor experiments and studies to evaluate Laetrile as any drug. Back in 1977, Dr. Lewis Thomas, President of Memorial Sloan-Kettering Cancer Center in New York, said that "solid facts" about Laetrile should be obtained, urging that:

"A double-blind clinical trial be made at several institutions; that an epidemiologic study be made in which perhaps 10,000 patients treated with Laetrile be studied and; that the data derived from the various studies be reviewed by a committee of scientists and lay people to counter claims of possible bias."

Various such studies were begun and are being carried on by Sloan-Kettering and especially by the National Cancer Institute. It is quite likely, however, that the advocates of Laetrile will not be influenced by any studies condemning the use of Laetrile by medical or scientific committees.

A recently published volume entitled *Wholistic Dimensions in Healing* claims to be a "resource guide" explaining various alternative approaches to health care. In an introduction by Rick J. Carlson, he states: "The day is past when we could confidently turn to modern medicine for all or even many of our health needs. By most estimates, even conservative ones, medicine influences most indices of health only to about 10%. The remaining 90% is dependent on environmental, social, and cultural factors for which doctors and hospitals have little, if any, control. . . . People are now . . . looking for alternatives to what some perceive to be dinosaur—the modern medical system." The tenor of the book emphasizes a disillusionment with the prevention and treatment of disease by the medical profession and advocates a study and use of other methods and nonmedical groups in the promotion of health and the prevention and treatment of disease.

In these times and in our country, science and medicine, scientists and physicians, increasingly are being challenged and questioned. Though it may be difficult for us to swallow, we physicians must adapt to what we consider intrusions by ancillary professions in the medical care of "our" patients. The hospital no longer may be "the doctors' workshop" exclusively. Even more importantly, the public may believe that there are values more basic and important than science and medicine.

DeTocqueville over 100 years ago observed that many important issues finally end up for adjudication in our Supreme Court. It is amazing that the use of one drug is going to be reviewed by the Supreme Court. However, it is not the use of a single drug that will be determined, but basic constitutional rights as interpreted by the court. In our country the principle rests in our concept of the rights of the individual, that the State exists for the individual, not the converse, protected by a bill of rights. We are living in a period when institutions and professions are being questioned and challenged. Dr. Arnold S. Relman, Editor of *The New England Journal of Medicine,* discussing *Wholistic Medicine* states: "A few years ago William G. Rothstein wrote an instructive history of *American Physicians in the Nineteenth Century,* which he subtitled 'From Sects to Science.' Let us hope that when the history of the wholistic movement in medicine comes to be written it will not be entitled 'From Science to Sects.' "

The message to the medical profession seems clear—that neither it nor its concept of medicine stands on the pinnacle of American public opinion, unquestioned and accepted as it was only a decade or two ago.

Fred Fabro, M.D.

# FROM THE EXECUTIVE DIRECTOR'S OFFICE

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## CALL
## ANNUAL MEETING OF THE HOUSE OF DELEGATES

**The 1979 Annual Meeting of the House of Delegates will be held at the Hartford Hilton Hotel, Hartford, commencing at 8:30 A.M. on Wednesday, May 2.**

**Jerome K. Freedman, President**
**Stuart Ragland, Jr., Speaker of the House**
**Louis C. Backhus, Secretary**

## INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides:

*Resolutions may be introduced by any Active or Life Member of The Society, in compliance with the following provisions:*

*a. All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*

*b. Component county associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc. be considered regular business if they are received later than fifteen days prior to the date of the meeting.*

*c. Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*

*d. Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provision of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

## PROPOSED AMENDMENTS TO THE BYLAWS

**The following proposed amendments to the Bylaws were presented to the House of Delegates on November 16, 1978 and were tabled for consideration and action at the next regular meeting of the House of Delegates.**

**In accordance with the Bylaws, these amendments will be published in *Connecticut Medicine* "on one or more occasions prior to the next meeting . . . at which meeting the amendments shall be taken off the table and acted upon by the House of Delegates."**

### LIFE MEMBERSHIP AND STUDENT MEMBERSHIP
### PURPOSE

To expedite and simplify the approval of Life Membership and Student Membership. (Delete underlined words and add words in capitals.)

### ARTICLE IV—MEMBERSHIP

Section 4. Life Members. Par. 1. A physician eligible for Life Membership may apply for such membership to the Executive Director of the Society and shall become a Life Member on approval by the Council EXECUTIVE DIRECTOR of such application.

Section 5. Student Members. Par. 1. Such membership shall be obtained by applying to the Council EXECUTIVE DIRECTOR'S OFFICE on a form provided for that purpose and election by vote of a majority of the Council SHALL BECOME A STUDENT MEMBER ON APPROVAL BY THE EXECUTIVE DIRECTOR OF SUCH APPLICATION.

### COUNCIL MEETINGS
### PURPOSE

To reduce the size of the quorum for Council meetings. (Delete underlined words and add words in capitals.)

### ARTICLE VII—THE COUNCIL MEETINGS

Section 5. Par. 2. Quorum. A quorum shall consist of more than 50% ONE-THIRD PLUS ONE of the voting members of the Council, with representation from at least five Counties.

### VACANCIES AND INTERIM APPOINTMENTS OF COMMITTEES

PURPOSE

To expedite and simplify the acceptance of resignations from, and appointments to, CSMS committees, etc. (Delete underlined words and add words in capitals.)

### ARTICLE XI—STANDING COMMITTEES REPRESENTATIVES AND ADVISORS OF THE HOUSE OF DELEGATES

Section 1. Purpose and Election. Par. 6. Vacancies and Interim Appointments. In the event of a vacancy on any standing committees or in the posts of representatives and advisors, the Council PRESIDENT shall fill such vacancy IF NECESSARY by appointment and the member appointed shall serve until the next annual meeting of the House of Delegates. In its HIS discretion, the Council PRESIDENT may also appoint additional members to serve on standing committees and as representatives and advisors, provided that such appointments do not exceed the numerical strengths stipulated by the House of Delegates. Members so appointed by the Council PRESIDENT shall serve until the next annual meeting of the House of Delegates.

### COUNCIL'S POWER TO FILL VACANCIES

PURPOSE

To clarify the wording to conform with filling of vacancies in committees, etc.

### ARTICLE VII—THE COUNCIL

Section 6. Power to Fill Vacancies. (Delete underlined word and add word in capitals.)

The Council shall have power to fill any vacancy which may occur in any elective office, board, or committee, for which the power to fill such vacancy is not otherwise provided, until the next regular ANNUAL meeting of the House of Delegates.

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## Council Meeting

Wednesday, January 10, 1979

### Attendance

Present were: Drs. Freedman, Kamens, James, Backhus, Spitz, Ragland, Jr., Friedberg, Hess, Fabro, Canzonetti, Cramer, Van Syckle, Sadowski, Magram, Eslami, Zlotsky, Beck, Rosenthal, Horrax, J. Barnett, Parrella, Tierney, F. Barrett, Sonnen and Bates.

Also present: Ms. Randell (Wiggin & Dana), Mr. Tomat (FCMA), Mrs. Lindquist, Mr. Sweeney, Mr. Brunell and Mr. Norbeck.

### Reports from Physicians Serving on State and Federal Agencies, Inc.

*HSA's*: Orvan W. Hess reported that HSA II has received support for another year and other plan developments; also, that a need for additional podiatric services was expressed in the HSA plan. The recommendations of the five HSA's have been gathered by the State Health Planning & Development Agency of SHCC which will issue the State Health Plan, which will be put to hearings during the next two months. The State Plan is supposed to reflect and coordinate the Health Service Plans of the five HSA's. *PSRO Statewide Council:* Isadore H. Friedberg discussed the recent meeting with physician representatives of the four PSRO's, and his attendance, along with several CSMS officers at a meeting with Congressman William R. Cotter (District 1) of Connecticut. *SHCC:* Edward A. Kamens reported on the recent HSA I hearing which accentuated a thrust toward outpatient surgery and commented briefly that SHCC following the hearings will review the State Health Plan. He further reported on a meeting with Congressman William Ratchford (District 5) of Connecticut. *CSMS Pamphlets*: Tim Norbeck reported that the Society has received an overwhelming public response to the pamphlets and that orders have been received from libraries, schools, and physicians. Acknowledgment letters have also been received from state legislators.

### Report of the President

President Freedman reported on his activities since the December Council meeting and mentioned that he had recently presented testimony to the Connecticut Commission on Hospitals and Health Care relative to the Commission's efforts to impose unreasonable new regulations which would penalize hospitals for increased admissions.

He reported to the Council on a letter recently received from Dr. Joseph M. Danyliw, East Hartford, relating to the problem of the interpretation of procedure codes used in determining Social Services payments to physicians. After a general discussion about the Department of Social Services, it was VOTED to have Mr. Norbeck and Dr. Freedman draft a letter to the Department pointing out past and current Society cooperation and that the inflation factor and continuing viability of the program warrants consideration of revisions in the payment schedules.

### Subcommittee on Administrative Organization and Planning

Guy W. Van Syckle, Chairman of the subject subcommittee, gave a progress report on his most recent meeting. It was agreed that the implementation date for the recommendations, concerning committee structure, as approved by the House of Delegates would be the 1979 Annual Meeting of CSMS and that a grandfather clause would be observed to go into effect at that time.

### Committee on Statewide Medical Planning

After considerable discussion of the subject committee's recommendation to employ additional staff, it was VOTED to direct Mr. Norbeck to prepare and submit his plan for additional staffing as soon as possible in order to carry out the Council's desire to implement a mechanism to deal with government agencies plus any other needs which need be addressed impacting on the practice of medicine.

### Cardiac Rehabilitation

After consideration of the request of Dr. Joseph P. Liss, Jr., for Society endorsement of the extension of the St. Francis Hospital and Medical Center Outpatient Cardiac Rehabilitation Program to the Hartford YMCA, it was VOTED that the principle of endorsing the quality and appropriateness of any medical program could be an awesome task in magnitude and should not be accepted as a responsibility of the Connecticut State Medical Society.

### Committee on Emergency Medical Services

It was VOTED to authorize the CSMS Committee on Emergency Medical Services to inquire of Governor Grasso as to the status of the Commission on Emergency Communication.

### Membership on AMA Councils

It was VOTED to nominate the following physicians for the designated AMA Councils:

J. Alfred Fabro, M.D.
  Council on Medical Service
Jerome K. Freedman, M.D.
  Council on Continuing Physician Education
E. Tremain Bradley
  Judicial Council
Orvan W. Hess, M.D.
  Council on Scientific Affairs and National Council for Evaluation of Medical Technology

### Liaison Representative to U.S. Department of Agriculture Rural Development Committee (Conn.)

It was VOTED to accept Dr. George M. Rosenfeld's resignation as the CSMS representative, with thanks, and to appoint Dr. John J. Barrett, Torrington, as the new CSMS liaison representative to the U.S. Department of Agriculture Rural Development Committee

### Connecticut Advisory Council for Emergency Medical Services

It was VOTED to appoint Dr. Edward R. Browne, Willimantic, as the CSMS representative to the Connecticut Advisory Council for Emergency Medical Services.

### Report from Committee on Hospitals

It was VOTED that the Society endorse the recommendations of the Committee on Hospitals to support the Connecticut Hospital Association position on acute care bed planning for the future.

### Statistical Survey from Department of Health

It was VOTED that CSMS staff should direct a communication to Commissioner Lloyd objecting to the Statistical Survey accompanying the license renewal which should have indicated its voluntary nature and that physicians were not required to complete it.

### Connecticut General Life Insurance Company Part B Medicare Claims Office

It was VOTED to have Dr. Freedman and members of the Committee on Peer Review Systems accept the invitation of Thomas M. Feeney, M.D., Medical Consultant, and meet in the near future at Dr. Feeney's office.

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on January 10, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

## 186th ANNUAL MEETING OF THE CONNECTICUT STATE MEDICAL SOCIETY

**Hartford Hilton Hotel, Hartford**
**May 2, 3, 1979**

### PRELIMINARY PROGRAM

### WEDNESDAY, MAY 2
### ANNUAL MEETING OF THE HOUSE OF DELEGATES

7:30 REGISTRATION OF DELEGATES

8:30 CALL TO ORDER
OPENING SESSION
REFERENCE COMMITTEE HEARINGS

1:15 LUNCHEON

2:30 CALL TO ORDER
FINAL SESSION

### ANNUAL DINNER OF THE SOCIETY

SOCIAL HOUR 6:30 P.M. DINNER 7:30 P.M.

INAUGURATION OF INCOMING PRESIDENT
EDWARD A. KAMENS, FAIRFIELD

### THURSDAY, MAY 3
### GENERAL SCIENTIFIC PROGRAM
### SECTION MEETINGS

The theme for the general scientific program will be new drugs and techniques in clinical medicine. Following are the topics that will be presented:

- ANTIMICROBIAL THERAPY—THE STATE OF THE ART
- NEW DRUGS IN CARDIOVASCULAR DISEASE
- ANTI-ARTHRITIC DRUGS
- THE CLINICIAN, THE PATIENT AND TECHNOLOGY
- PROGRESS IN THE THERAPY OF THE INFLAMMATORY BOWEL DISEASE

Exhibits will also be presented and physicians should take advantage of the opportunity to review what is new and timely in medicine and related subjects.

# In Memoriam

**MAURER, WILLIAM S.,** Yale Medical School, 1938. Dr. Maurer was an internist in the Windham area until his retirement in 1975. He was an Army veteran of World War II, and joined the staff of Windham Community Memorial Hospital in 1946. He was very active in the hospital's cardiology department, and was a member of the Windham County Medical Association. He had served at Windham Community Memorial Hospital, at various times, as chief of medical services, and president, vice-president, secretary, and on the executive committee of the medical staff. He was a member of the Windham County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Maurer died December 14, 1978, at the age of 69.

**MORESCHI, FRANCESCO,** University of Bologna, Italy, 1951. Dr. Moreschi was an internist in the New Haven area since 1961. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Moreschi died November 9, 1978, at the age of 55.

**THOMPSON, MAURICE B.,** Physicians & Surgeons, New York, 1931. Dr. Thompson was a general practitioner in the New Haven area since 1932. He was a World War II veteran of the U.S. Army Air Force and a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Thompson died November 23, 1978, at the age of 74.

**WAWRO, N. WILLIAM,** Yale University School of Medicine, 1938. Dr. Wawro practiced medicine in the Hartford area since 1944. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Wawro died as the result of a car accident on the island of Maui, Hawaii, November 5, 1978, at the age of 64.

**WEXLER, HENRY,** Syracuse University, 1931. Dr. Wexler was a psychiatrist in the New Haven area since 1949. He served as a Major in the U.S. Army during World War II and was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Wexler died December 16, 1978, at the age of 72.

# Current Status of Platelet Transfusion Therapy

ALFRED J. KATZ, M.D. AND HERBERT SILVER, M.D.

Platelet transfusion has become a vital part of transfusion therapy. Infusion of platelets is effective in treatment of bleeding due to thrombocytopenia, particularly when thrombocytopenia is due to decreased platelet production. Prophylactic infusion of platelets is widely accepted, and in perhaps all but the most carefully controlled clinical settings is indicated to prevent thrombocytopenic bleeding. Platelet transfusion is not without risks; in addition to well recognized adverse reactions to transfusion in general, recipients of platelets become alloimmunized and refractory to further platelet transfusion. The appropriate selection of the platelet product for infusion, and the management of the alloimmunized recipient are current areas of greatest interest.

**Platelet Products:** Platelet concentrates may be separated from individual units of whole blood or may be collected in large quantity from individual donors by plateletpheresis. Further, the single donor products may be obtained from unselected donors, or donors selected for HLA type. Therefore, the techniques of preparation and the characteristics of the preparations are briefly reviewed. Platelet concentrates prepared from individual units of whole blood are separated by differential centrifugation, in a closed system, within four hours of collection. Platelets to be stored at 22°C are resuspended in approximately 50 ml of plasma, and are continuously mixed during storage. Federal Regulations require that platelet concentrates must maintain a pH above 6.0 during 72 hours of storage, and 75% of the units must contain greater than 5.5 X $10^{10}$ platelets. Those platelets which are recovered post-infusion survive normally and have been reported to be hemostatically functional within 2½ hours of infusion.[1] Available data suggests that about 80% of the stored platelets maintain the ability to circulate after three days of room temperature storage.[1] It is well recognized now that platelets stored in the cold for greater than 24 hours do not survive well after transfusion and are less effective hemostatically than the platelets maintained at room temperature.[1] [2] Platelet concentrates prepared by Connecticut Red Cross Blood Services have a mean content of 8.2 X $10^{10}$ (1S.D = 2.7) platelets per concentrate, are maintained in approximately 50 ml and may be transfused during the 72 hours following collection of the original unit of blood.

The most widely used technique for collecting platelets from individual donors is discontinuous flow centrifugation using the Haemonetics Model 30 cell separator. This is a more complicated, more time consuming procedure than separation of platelets from a unit of whole blood. Single donor platelet product contains 46 X $10^{10}$ platelets (± 12). If lymphocytes are removed, yield is 39 X $10^{10}$ (± 10). The donors used for the plateletpheresis procedure may be selected from patient family members or can be selected from a donor file. Connecticut Blood Services currently has a file of about 1,000 HLA typed, non-family member donors available for this procedure. There is need to increase the number of typed donors in the near future.

**Indications for Platelet Transfusion:** In general, platelet therapy is indicated when there is underproduction of the element, or when there is bleeding due to an intrinsic platelet functional disorder. Infusion in the presence of an enlarged spleen, or in the presence of increased destruction is not effective; a platelet must circulate to be helpful. However, temporary platelet support may be useful during massive transfusion with bank blood. When circulating platelets have normal function, and when thrombocytopenia is not complicated by other hemostatic difficulties, spontaneous bleeding is not likely to occur until the platelet count is 20,000/µl or less.[3] Increased oozing may be present at surgery without excessive or uncontrolled blood loss at levels of 30,000 to 50,000 platelets/µl. Platelet counts can be

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ALFRED J. KATZ, M.D., Director, Connecticut Red Cross Blood Services; Associate Professor of Laboratory Medicine, University of Connecticut School of Medicine, Farmington.

HERBERT SILVER, M.D., Director, Blood Bank and Immunohematology, Hartford Hospital.

deceptively comforting if medication affecting platelet function, such as aspirin, has been taken, or if the patient has a disease which affects platelet function.

**Post Transfusion Response:** Post transfusion increment of platelets in the recipient depends upon many variables, including the number of viable platelets infused, the blood volume of the recipient, and the recipient's clinical status. Those variables relevant to the recipient's clinical state include active bleeding, infection, fever, splenomegaly, and presence of any other condition which would be expected to increase platelet destruction. In the stable recipient, approximately 30% of infused platelets will not appear as peripheral blood increment because of normal splenic trapping. In the stable recipient, the expected post transfusion increment is a function of blood volume, and can be predicted. For example, given an infusion of ten platelet concentrates of $7 \times 10^{10}$ platelets per concentrate, to an individual with a 5,000 ml blood volume, there will be an expected increment of 90,000 platelets per microliter. A stable recipient in whom the increment is less than or equal to half of that expected can be considered refractory to further random platelet infusion;[4] that is, post transfusion platelet increments will be minimal after the infusion of random platelet concentrates. These estimates, of course, assume that other variables leading to decreased recovery are not present.

Routine use of platelets has been associated with a marked decrease in death from thrombocytopenic bleeding in leukemic patients.[5] The standard of practice, certainly, is to transfuse platelets prophylactically to leukemics who are thrombocytopenic and who are at risk of bleeding - usually at a level of 20,000 platelets per microliter or less. It has been reported [6] [7] that prophylactic infusion of platelet concentrates is effective in decreasing the frequency of bleeding, even if the platelet count of the recipient is not raised.[6] It has more recently been reported that with careful clinical and laboratory observation of adults with acute leukemia, it is possible to reduce by one half the amount of platelets transfused with no difference in complete or partial remission, number of deaths, or number of bleeding deaths.[8] This caution raised in the use of platelets has also been echoed in a review of platelet use in pediatric oncology.[9] In 30 patients given 393 platelet transfusions, only 33% of transfusions led to an adequate platelet rise post transfusion. Platelet transfusion to control bleeding was successful only 40% of the time. The primary factor precluding success was the number of previously administered platelet transfusions. This study serves to emphasize the particularly disconcerting adverse effect of repeated platelet transfusion, that is alloimmunization.

**Selection of the Appropriate Platelet Product:** Most platelets produced for transfusion are those separated by differential centrifugation from units of whole blood. These platelets have advantages of availability, and ability to be prepared within a closed, sterile system and to be stored for up to three days prior to infusion. Single donor platelets from plateletpheresis may be available to supplement this inventory of random donor platelet concentrates. While the single donor product should represent a lower hepatitis risk for the recipient, other advantages attributed to this product are not substantiated at this time. It has yet to be demonstrated that the infusion of platelets from single donors is less likely to alloimmunize the recipient. There is also no evidence that the single donor product provides functionally better platelets. Therefore, for virtually all patients in need of platelet transfusion, the initial product of choice is the random unit concentrate.

The recovery of platelets may be reduced by ABO incompatibility, but those platelets recovered in the circulation survive normally.[10] However, the presence of contaminating erythrocytes with their ABO antigens, and the presence of anti A and or anti B in plasma in which the platelets are suspended may be more important considerations. Similarly, the Rh antigens on these contaminating red cells may be of concern in transfusion to a non-immuno-suppressed recipient, particularly a young woman. For these reasons, whenever inventory permits, ABO compatible concentrates are distributed. (Maintenance of separate inventories of platelets on the basis of ABO type would lead to enormous waste of this resource.) Individual clinical situations obviously require individual selection of the product.

The single donor plateletpheresis product is therefore primarily used for transfusion to a refractory recipient. The best approach to the selection of a donor whose platelets will survive successfully is the selection of that donor on the basis of the HLA -A and -B loci. Even with the selection on the basis of HLA type, there is still considerable individual variability in transfusion results[11] suggesting that other antigens may be important. Therefore, empiric platelet crossmatch procedures have been evaluated. These have included platelet aggregation, lymphocyte cytotoxicity, platelet serotonin release, and most recently platelet immuno-florescence.[12] [13] [14] [15] There is no current concensus on the value of any of these procedures.

Removal of contaminating lymphocytes from the platelet preparations may delay the onset of a refractory state and in fact may reverse it. It has been reported that if leukocytes are removed by differential centrifugation and if platelet recipients are transfused with white cell free red cell preparations, then 70% of patients will respond to platelet transfusions after 2-6 months of therapy, in comparison to a majority who become refractory within two months of initiating platelet therapy with products containing lymphocytes.[16] Herzig, et. al. have reported that given fixed donor-recipient pairs, removal of the lymphocytes can reverse the refractory state, can eliminate accompanying transfusion reactions, and can prolong the donor-recipient state of compatibility.[17] Freezing platelets collected from alloimmunized recipients while they are in remission is another strategy, but one not yet widely available.[18] Platelet transfusion therapy has moved within the last decade from non-availability of sufficient concentrates to full, if not surplus, capacity. Platelet transfusion has maintained an important therapeutic role, but care must be taken to transfuse in appropriate circumstances and to minimize alloimmunization when possible. Development of appropriate strategies to manage the alloimmunized recipient effectively remains the current challenge.

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# Clinical Effectiveness of Granulocyte Transfusions

EDWARD E. MORSE, M.D. AND ALFRED J. KATZ, M.D.

## Introduction

Transfusion of granulocytes has been demonstrated to control infections, particularly septicemia, in animals and man. In some of the earliest studies, Brecher and colleagues[5] showed that transfused granulocytes migrate to sites of infection in irradiated neutropenic dogs. Smith[19] showed that in neutropenic rats, the dose of intravenous pseudomonas required to kill 50% of the animals was dependent upon the circulating neutrophil level. More recently Tobias and Yankee et al[20] showed that granulocyte transfusions given just prior to injection of $10^9$ E. Coli in neutropenic irradiated rats prevent death from septicemia.

Appelbaum[2] found that beagles made neutropenic with cyclophosphamide survived intravenous injection of higher concentrations of pseudomonas when they were transfused with granulocytes four hours later. All control animals died 3-5 days after injection of $1 \times 10^8$ bacteria/kg while all animals survived if they received $2 \times 10^8$ granulocytes/kg prepared by continuous flow centrifugation or $5 \times 10^8$ granulocytes kg prepared by filtration.

Epstein[18] discovered that the number of candida organisms was markedly reduced in the tissues of neutropenic dogs which had been transfused with granulocytes shortly after the candida septicemia was introduced. The granulocyte concentration increased in the circulation with three to four daily transfusions while it remained very low in control dogs. Liver and other tissue was collected from transfused and control dogs and the number of organisms per gram of tissue was markedly reduced in transfused animals.[9]

In man, studies relating the risk of bacterial infection to circulating granulocyte level had been reported by Bodey, et al[3] showing that circulating levels below 500/cmm carry higher risk of septicemia and other serious infection. The first human granulocyte transfusions were given using cells from donors with CML separated by simple bag pheresis.[15] CML cells survived longer in the circulation than did normal granulocytes and it was possible to elevate the circulating granulocyte levels by repeated transfusions. The data indicated there was an important relationship between the likelihood of the patient showing defervescence and the dose of granulocytes given. After a dose of $1 \times 10^{11}$ granulocytes (approximately the normal daily turnover) virtually all the patients recovered. Furthermore, if the first transfusion failed to produce a response, a second or third daily transfusion frequently did even in the presence of pseudomonas septicemia.

## Granulocyte Separation Techniques

The use of normal granulocytes for transfusion has been made possible only by the development of new separation techniques utilizing continuous flow centrifugation[12] or filtration techniques,[1 6 8] and subsequently intermittent flow centrifugation.[14]

Filtration techniques have consistently given the highest doses of granulocytes.[1 8] The donor is given heparin in small doses to prevent coagulation as the blood is pumped through nylon wool filters. A full blood volume of six to seven liters can be filtered in two to three hours. The granulocytes are then eluted from the filters with a solution containing acid citrate, dextrose (ACD), 20% plasma and saline (with gentle agitation). By this technique, about $2 \times 10^{10}$ granulocytes can be obtained, with few red cells and little platelet contamination. Microscopic examination reveals that many of the granulocytes appear damaged and vacuolated after elution.[17] Centrifugation on the other hand requires that a plasma expander, hydroxyethyl starch, be added along with

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ACD anticoagulant to cause rouleaux of the red cells and improve separation of the granulocytes. Donors also are given dexamethasone and prednisone to increase the circulating granulocyte level and increase yields. Intermittent flow centrifugation using Haemonetics Model 30 centrifuge yields about 1 X $10^{10}$ granulocytes with substantial red cell and platelet contamination. The granulocytes appear intact however.[16] Continuous flow centrifugation has yielded average doses of less than 1 X $10^{10}$ in some institutions[10] but as much as 3 X $10^{10}$ in others.[21] The latter doses have been obtained only after prolonged pheresis (4-6 hours) of relatives of patients.

### Functional Studies

Studies of chemotaxis,[4] phagocytic ability, and bacteriocidal activity in vitro by several different investigative groups[16, 17, 22] have shown significant differences in vitro between filtered and centrifuged granulocytes. Wright et al[22] showed reduced chemotaxis in filtered granulocytes which became worse depending upon the length of the filtration procedure and the vigor of agitation of the filters during the elution phase.

Our own studies have revealed reduced chemotaxis and bacteriocidal capacity in granulocytes obtained by filtration when compared with those separated by intermittent centrifugation. (Table 1)

In vivo transfusion studies have shown that filtered granulocytes leave the circulation more rapidly than centrifuged granulocytes[12, 13] and that larger doses are required in animal studies to obtain equivalent therapeutic effect compared with centrifuged granulocytes.[2]

Table 1

| *Chemotaxis* | *Cells/10 HPF (n)* | *Significance* |
|---|---|---|
| Control Dextran Sedimented | 333 ± 219 (11) | — |
| Centrifuged Granulocytes | 288 ± 139 (6) | NS |
| Filtered Granulocytes | 173 ± 111 (17) | p < .02 |
| *Bacteriocidal Activity* | *% Inhibition* | |
| Centrifuged Granulocytes | 83 ± 10 (12) | p < .01 |
| Filtered Granulocytes | 66 ± 13 (11) | |

### Human Experience

Studies of granulocyte transfusions in man have shown that doses of $10^{11}$ or 100 billion cells are almost 100% effective in clearing infection,[15] but such doses can be obtained only using donors with chronic myelocytic leukemia, with peripheral white counts of over 100,000 per $\mu$l. Using normal granulocytes which are available in doses of 1-3 X $10^{10}$ or ten to thirty billion cells, it is necessary to transfuse on a daily basis for four or more days to achieve a high degree of therapeutic success.[12] At Connecticut Red Cross Blood Service, two techniques are used to provide granulocytes for transfusion. Filtration leukopheresis yields a mean of 1.5 ± 0.7 (SD) X $10^{10}$ granulocytes per transfusion. Centrifugation leukopheresis using the Haemonetics Model 30 yields a mean of 1.0 ± 0.3 (SD) X $10^{10}$ granulocytes per transfusion.

Our transfusion experience using ABO matched but not HLA matched donor granulocytes indicates that 67% of all patients treated in Connecticut recover from their infection if they receive four or more transfusions. The average course of transfusion is seven days. There appears to be no difference in recovery rate whether filtration cells or centrifuged cells are used when the entire population of patients is considered. However, a small group of patients with acute leukemia transfused during their first course of chemotherapy did show a significantly better recovery rate with centrifuged cells than with filtration cells. This was a retrospective study and attempts to confirm the observation prospectively must be undertaken. Most of the newer techniques for the separation of granulocytes for transfusion are utilizing centrifugation principles. Whether HLA matching will improve recovery also needs further study.[11]

Criteria for selection of patients for transfusion should include a circulating granulocyte level of less than 500/cmm expected to last 7-10 days, fever, evidence of infection, no response to antibiotics for 1-2 days (unless infection is obvious, and the patient is critical), and a reasonable likelihood of useful life if the patient recovers from the infection.

Current evidence suggests patients most likely to benefit from granulocyte transfusions are those with proven septicemia,[13] whose bone marrow depression is temporary and who will obtain a remission within 1-2 weeks.[1, 10, 13, 21]

Transfusion of granulocytes to patients with hyperplenism, or immunologically induced (destructive type) neutropenia, wide spread cancer or leukemia not responding to chemotherapy, is not warranted and is a waste of an expensive blood resource.

Prophylactic granulocyte transfusions have been reported to be efficacious in special situations.[7, 20] In animals, giving granulocytes just prior to injecting bacteria, prevents death from septicemia in 65% of the animals. In marrow transplant recipients, transfusion of HLA matched granulocytes from relatives appears to prevent infection until the marrow graft takes. Further studies are in progress in several centers funded by the Federal Government to determine the application of prophylactic granulocyte transfusions. Routine use of prophylactic granulocytes is not warranted at this time.

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# Clinical Aspects of Autologous Transfusion

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## Introduction

There has been considerable change in technique and method of transfusion since Jean Baptiste Denis, in 1667, successfully transfused the blood of a lamb into a patient. A subsequent attempt, incidentally, was not so successful and led to what may be considered the first recorded case of a malpractice conviction. The transfusion of homologous donor blood which is so prevalent today is an off-shoot of Denis' heterologous technique and still anything but completely safe. Karl Landsteiner's discovery of the ABO blood group system in 1900 helped to reduce the risk of transfusion but by no means eliminated it. Since Landsteiner's discovery, over 250 additional blood factors have been identified. Considering these factors alone it is calculated that there is less than a one in 100,000 chance of selecting an exactly matched donor-recipient combination. It is apparent that compatibility testing cannot completely eliminate the hazard of mismatched blood.

A mechanism for accomplishing entirely safe transfusion was described in 1818 by John Blundell[1] when he reported on the transfusion of ten women with post-partum hemorrhage. The blood used had been collected by means of intraoperative salvage. For the most part, little serious attention was paid to this first description of autologous transfusion although sporadic reports of successful transfusion of shed blood did appear in the medical literature throughout the 1800's.

The first documentation of autologous transfusion in elective surgery was by F.C. Grant in 1921.[2] He introduced preoperative collection of blood which was made practical by using sodium citrate as an anticoagulant. The blood was refrigerated overnight and reinfused during surgery the following day. This was followed by sporadic reports by other physicians which documented successes with autologous transfusion. In most of these instances an intraoperative salvage technique was employed, predominantly in ectopic pregnancy or trauma.

It was not until the 1960's that autologous transfusion was given the attention it deserves. Vermuelen-Cranch[3] in 1962 wrote of experiences using preoperative autologous donations; Langston et al[4] in 1963 reported using the technique in elective surgery; in 1967 Cuello[5,6] published two papers on autologous blood transfusion in cardiovascular surgery; Hardesty[7] in 1968 described the use of autologous fresh blood during open heart surgery. The most extensive review of experiences can be found in the John Alexander Monograph Series.[8]

Autologous transfusion refers to the intravenous administration of blood or blood components into the individual (donor) from whom it was obtained. This is in contrast to homologous transfusion in which donor and recipient are not the same and heterologous transfusion where there is a species difference. Autologous transfusion is often referred to incorrectly as autotransfusion which actually means the act of transfusing oneself. The term autologous, from the Greek "autos" and "logos," means related to self.

There are three major clinically applicable forms of autologous transfusion:

1. preoperative blood collection and storage (predeposit) with reinfusion during or after surgery
2. intraoperative blood collection followed by hemodilution with reinfusion during or following surgery
3. intraoperative salvage of blood and reinfusion during surgery

The three methods can be used individually or in combination. Although they reduce the need for homologous blood, they may not eliminate the need completely. In any case, they offer distinct advantages over the use of homologous donor blood with few if any disadvantages.

## Predeposit

Predeposit prior to elective surgery is the most generally applicable method of collecting blood for

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autologous transfusion. The number of units collected can be varied according to anticipated needs, the date for surgery or, for that matter, any other procedure which may require blood transfusion, and the condition of the donor. Children as well as senior citizens may be suitable candidates for transfusion. It is not uncommon to collect autologous units from children as well as from adults who are to undergo corrective orthopedic surgery. Units can be collected from older adults on whom a coronary bypass procedure[9] or other cardiac surgery is to be performed. Only those cardiac patients with preinfarction type angina, a history of congestive failure, or a mainstem coronary artery lesion are not acceptable for collection of blood for autologous transfusion. Pregnant patients may be ideal candidates if the pregnancy is uncomplicated and even dialysis patients can have blood stored to fill future needs if they should arise.

There are, of course, certain considerations before a patient (donor) can be accepted in a predeposit program. The hematocrit (hemoglobin concentration) is a major factor which must be taken into account. It must be at least 34% (hemoglobin 11g/dl) prior to each donation. Iron is the rate-limiting factor in hematopoiesis following phlebotomy but oral iron therapy, 325 mg three times each day, instituted several days prior to or immediately following initial phlebotomy is usually adequate to maintain hematocrit levels.[9] [10] From one to four units of blood can then be easily withdrawn within a three-week period with less than a 3% drop in hematocrit during this period in most cases. The interval between donations and between the final donation and surgery can vary. It is recommended that donations should be no more frequent than every three days. Usually 72 hours is the maximum time required to mobilize sufficient protein to return the intravascular volume to normal following venesection or any other type of acute blood loss.[11] In most cases, 24-48 hours are sufficient. With collection intervals of 72 hours, four units of autologous blood could be easily collected and stored in a conventional blood bank refrigerator within the 21-day outdating period for blood. Under some circumstances, with suitable fluid replacement, an autologous unit of blood can be collected safely 24 hours prior to surgery.

The ability to store blood in the frozen state, although not essential or even necessary to the establishment of a predeposit program, can increase the potential and applicability of a predeposit program as it eliminates the need to collect blood within a three-week period. Current FDA regulations allow storage in the frozen state for up to three years. Therefore, blood can be collected over a matter of weeks, months or even years. Another advantage to frozen storage of blood is that higher levels of 2,3-diphosphoglycerate (2,3-DPG) are maintained. The levels remain the same as on the day the unit was frozen rather than gradually decreasing over the period of storage as occurs when kept at 1° to 6°C. Whether this is truly significant from a physiologic standpoint is still to be determined.

There are some drawbacks to the use of frozen blood for autologous as well as homologous transfusion. The process of freezing is more expensive than liquid storage (Table 1) and generally unavailable except in larger centers. Costs, approximately $80-$90 for a single unit in comparison to about $30 for whole blood, are high but they can be reduced if several units are reconstituted for one individual at a time (Table 2). Furthermore, reconstitution of each unit takes approximately 30 minutes. Following reconstitution, infusion must occur within 24 hours as this is required by current FDA regulations concerned with units of blood processed in an open system. Consequently, frozen blood often is not convenient for standby surgical use.

If autologous units have been thawed and reconstituted or if blood stored in the liquid state is approaching the outdate time, and surgery or any other intended use for the blood has been delayed, units which are soon to outdate can be replaced by fresh units by a technique called "leap-frogging." Employing this method a unit of blood is withdrawn from the patient and the oldest unit is reinfused. This can be repeated and continued as long as necessary. The same technique can be used to obtain a supply of relatively fresh whole blood to satisfy cardiovascular surgeons who feel the blood they use needs to be two

Table 1

COST† (DOLLARS) OF COLLECTION AND LIQUID STORAGE OF 1-4 UNITS OF AUTOLOGOUS BLOOD

| *Visits* | *1** | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Unit of Blood* | | *1st* | *2nd* | *3rd* | *4th* |
| Technician TimeΔ | 6.50 | 6.50 | 6.50 | 6.50 | 6.50 |
| Collecting Bag | | 2.39 | 2.39 | 2.39 | 2.39 |
| Donor Blood Tests | | | | | |
| Hematocrit | 1.30 | 1.30 | 1.30 | 1.30 | 1.30 |
| Others** | | 15.80 | 15.80 | 15.80 | 15.80 |
| Miscellaneous | | 1.50 | 1.50 | 1.50 | 1.50 |
| Total | 7.80 | 27.49 | 27.49 | 27.49 | 27.49 |

Total Cost (4 units and initial evaluation) - $117.76

Average Cost per Unit - $ 29.44

† Does not include administrative and facility overhead

* Visit one is for evaluation and scheduling

Δ Interview, collection and processing at $6.50/hr.

**ABO, Rh, IAT, HB$_S$Ag, VDRL

Table 2

COST† (DOLLARS) OF COLLECTION AND RECONSTITUTION OF 1-4 UNITS OF FROZEN AUTOLOGOUS BLOOD

| *Visits* | *1** | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Unit of Blood* | | *1st* | *2nd* | *3rd* | *4th* |
| Technician Time Δ | 6.50 | 16.25 | 14.62 | 14.62 | 14.62 |
| Materials | | | | | |
| Collection and Freezing Bags | | 7.39 | 7.39 | 7.39 | 7.39 |
| Freezing and Washing Fluids | | 10.10 | 10.10 | 10.10 | 10.10 |
| Wash Bowl and Harness | | 24.25 | — | — | — |
| Transfer Pack and Waste Set | | 2.71 | 2.71 | 2.71 | 2.71 |
| Donor Tests | | | | | |
| Hematocrit | 1.30 | 1.30 | 1.30 | 1.30 | 1.30 |
| Other ** | | 15.80 | 15.80 | 15.80 | 15.80 |
| Miscellaneous | | 1.50 | 1.50 | 1.50 | 1.50 |
| Total | 7.80 | 79.30 | 53.42 | 53.42 | 53.42 |

Total Cost (4 units and initial evaluation) - $247.36

Average Cost per Unit (4 units collected) - $ 61.84

† Does not include administrative and facility overhead

* Visit one is for evaluation and scheduling

Δ Interview, collection, processing, freezing and thawing at $6.50/hr.

**ABO, Rh, IAT, $HB_sAg$, VDRL

to three days old at most. To meet these demands multiple phlebotomies and infusions would be necessary until two to three days prior to surgery. The more routine type of "leap-frog" procedure is generally well-tolerated by the donor although it is somewhat time consuming.[12] This adds to the unit cost (Table 3), but other advantages far outweigh this consideration.

The advantages of a predeposit autologous blood program are considerable. A program of this type could eliminate the complications of homologous donor blood transfusion for those participating. Many of these complications, such as hemolytic transfusion reaction, hepatitis, allergic reactions and reactions to donor white cells, are potentially fatal. To a lesser degree, the complications can make the patient, and perhaps the physician who has ordered the transfusion of homologous blood, extremely uncomfortable. Testing of homologous units can reduce the likelihood that a transfusion reaction will occur but it does not eliminate it. Febrile and allergic reactions will continue to occur. Approximately 2% of the homologous units infused can be expected to result in a transfusion reaction of varying intensity. At Hartford Hospital 75-100 reported transfusion reactions occur each year. None have ever been attributed to the 3,150 autologous units administered over the past six years.

Table 3

COST† (DOLLARS) OF COLLECTION AND LIQUID STORAGE WITH "LEAP FROG" OF 4 UNITS OF AUTOLOGOUS BLOOD

| *Visits* | *1** | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Unit of Blood* | | *1st* | *2nd* | *3rd* | *4th* |
| Technician Time Δ | 6.50 | 6.50 | 13.00 | 13.00 | 13.00 |
| Materials† † | | 2.39 | 13.58 | 13.58 | 13.58 |
| Donor Blood Tests | | | | | |
| Hematocrit | 1.30 | 1.30 | 1.30 | 1.30 | 1.30 |
| Others** | | 15.80 | 15.80 | 15.80 | 15.80 |
| Miscellaneous | | 1.50 | 1.50 | 1.50 | 1.50 |
| Total | 7.80 | 27.49 | 45.18 | 45.18 | 45.18 |

Total Cost (4 units and initial evaluation) - $170.83

Average Cost per Unit - $ 42.70

* Visit one is for evaluation and scheduling

Δ Interview, collection, processing and leap frog procedure

††CPD single bag; ACD double blood pack; recipient set

**ABO, Rh, IAT, $HB_sAg$, VDRL

† Does not include administrative and facility overhead

Another advantage to an autologous blood program is that predeposited units which are not used can be released for homologous use with the consent of the donor and physician if the donor meets usual donor standards. Many do meet these standards although that they do so is not required for an autologous donation. To qualify for autologous collection the donor must only be in sufficient good health so that the predeposit phlebotomies will not be unduly hazardous.[13] This is decided by the donor's physician who must submit a written request for the phlebotomies to be done and by the physician in charge of the donor room who maintains final responsibility for the donor. Age is not a serious consideration and the amount of blood to be taken can be adjusted according to the size of the donor. Therefore, pediatric patients can benefit from this type of program as well.

If all surgical patients are encouraged to predeposit blood, whether or not blood loss is anticipated, the community blood supply could be improved considerably. But even more important, in the event of an unexpected need for blood by the patient units will be available and the requirement for homologous blood transfusion with its inherent problems may be eliminated.

Predeposit and subsequent autologous transfusion may have had a unique application and may have resulted in a distinct advantage to at least one of the participants in the 1976 Summer Olympics. Charges of "blood doping" surfaced during the games and involved a Scandinavian long distance runner who unexpectedly won his race. Although nothing unethical was uncovered, a possible explanation for the unusual performance might be found in a study reported by Ekblom et al.[14] a Swedish research team. The participants in the study predeposited 800 to 1,200 ml of blood at the outset. Within 14 days the hemoglobin of all those who had been bled returned to control levels. Four weeks following the last venesection autologous red cells were reinfused. The following day a 23% increase in physical performance capacity during exhaustive running was demonstrated. Although clinical application of the results of this study may be somewhat limited, it does seem to indicate that there could be some added benefit to a patient beyond eliminating the homologous transfusion, as well as to a runner, from predeposit with autologous transfusion following some time later.

### Intraoperative Collection and Hemodilution

Although more limited in application than predeposit, intraoperative collection of blood for autologous transfusion is frequently used at centers doing coronary artery surgery. The units collected are replaced by crystalloid solutions (Ringer's). This results in a hemodilution of varying degrees. Consequently, there is a considerable reduction in the number of red cells lost during operative bleeding with a subsequent decrease in the need for blood. Postoperatively, blood replacement is accomplished with fresh autologous units rich in platelets and 2,3-DPG.

The autologous units are collected just prior to the introduction of the extracorporeal circulation. They are replaced with three times the volume in crystalloid. The procedure varies from institution to institution in the number of units removed and the degree of hemodilution. In some centers two units of blood (1,000 ml) are withdrawn routinely. Other protocols call for the removal and replacement of up to 20% of the patient's blood volume. This could result in hematocrits of 30% after phlebotomy and in the range of 15% during bypass.[15] At the Massachusetts General Hospital when 2 units were taken routinely a reduction in homologous blood needs of approximately 25% resulted[16] with no increase in patient mortality or morbidity.

### Intraoperative Salvage

One of the more recent innovations in autologous transfusion, intraoperative salvage, is basically a modification of the procedures used when early attempts at transfusion were made in the 1800's. Today intraoperative salvage still entails, for the most part, the recycling of blood which has been lost through hemorrhage into a closed cavity. The hemorrhage may have resulted from a ruptured aneurysm or an ectopic pregnancy, for example, or it may have been hemorrhage following surgical intervention. As in the past, the blood shed by the patient is collected, filtered and reinfused, but rather than scooping the blood up with a cup and draining it through gauze to remove clots the newer apparatus in use provides a means for suctioning the blood, washing it using a centrifuging technique, and then filtering it through special filters before reinfusing it. (Figure 1).

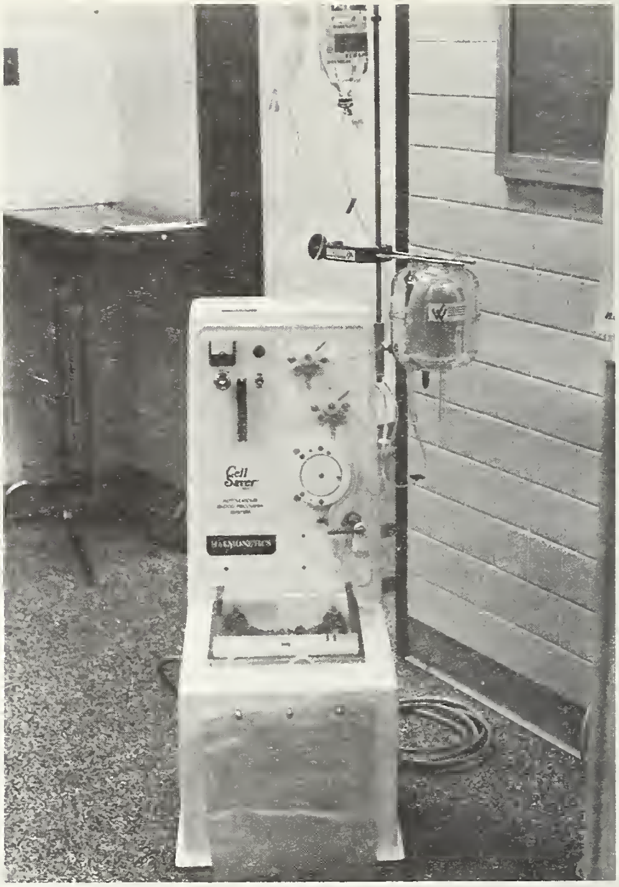

Figure 1

The equipment and the procedure initially used during intraoperative salvage caused several problems.

1. The red cells were traumatized and had a shortened life span. As a result, within several days of the infusion hemolysis was often evident and transfusion was required to bolster a decreasing hematocrit.
2. It was not uncommon for a hemorrhagic diathesis to occur postoperatively. This could be related either to the systemic heparin used to reduce clotting of the salvaged blood or to a disseminated intravascular coagulopathy (DIC).
3. Contaminants such as free hemoglobin and red cell phospholipids which may precipitate a DIC, body and tissue fluids, and fat and bone spicules which could result in pulmonary microemboli, were often infused. This was material which was suctioned from the cavity containing blood but which could not be removed by filtration as there was no provision for washing the cells.

Newer systems for intraoperative salvage not only filter but wash the red cells as well. The washing process removes debris and thromboplastic substances which could result in a hypercoagulable state. Only cells suspended in saline are infused so that heparinization of the patient becomes unnecessary. There have been no reports of significant adverse reaction directly attributable to blood salvaged in this manner.[17] Sepsis and metastasis remain a potential hazard if intraoperative salvage is inadvertently used in patients with infection and malignancy. Coagulopathies, if they occur, are dilutional in nature and can be corrected with appropriate component therapy.

There are several advantages which accrue from intraoperative salvage:

1. As there is no need to crossmatch salvagec blood in acute hemorrhagic emergencies, intraoperative salvage can eliminate delays resulting from routine as well as difficult crossmatches of homologous blood. It should be kept in mind that the salvaged blood is devoid of functioning platelets as they have been removed either by washing or filtration.
2. Problems arising when supplies of homologous blood are inadequate are minimalized as the major part of most massive blood losses can be replaced by the salvaged blood.
3. The red cells infused have presumably normal 2,3-DPG level and therefore oxygen is more readily released by the hemoglobin in these cells in contrast to red cells stored for a considerable time in the liquid state. Again it should be pointed out that the significance of this, from a physiologic standpoint and on a cellular level, is still in question.

## Conclusion

As long as the capability for collection and refrigerator storage of blood exists at an institution there is the potential for a successful autologous blood program. At the very least, a predeposit plan can be introduced with liquid storage of blood. If the introduction of such a program does not appear to be feasible because of the lack of personnel capable of collecting blood on other than an emergency basis, the services of the Red Cross can be used. Arrangements can be made for the collection and storage of autologous units and the return of these units when needed for patient care.

The advantages of an autologous blood program are numerous. The concept is relatively simple and the patient usually enters into the program enthusiastically when introduced to it by the primary care physician. The physician should consider it an obligation and responsibility to inform the patient that transfusion which is completely safe is available.

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# Non-Infectious and Non-Immunologic Complications of Blood Transfusion

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On March 15, 1937, Dr. Bernard Fantus opened the first blood bank in the United States at Cook County Hospital in Chicago.[1] Although the opening of this blood bank was a great achievement, death from improper blood transfusion remained a real danger. Accordingly, physicians were urged to exercise great care in the preparation and administration of banked blood.[2,3]

Much has been learned in the past 40 years about both immunologic and infectious complications of blood transfusions. There remain, however, many other transfusion related problems; this paper will discuss five of them: 1) microaggregates and microaggregate blood filters, 2) incompatibility of some crystalloid solutions with red blood cells, 3) blood warming devices and infusion of cold blood, 4) hypotension associated with the infusion of plasma protein fractions, and 5) hazards associated with the infusion of the plasticizer diethylphthalate during blood transfusion.

### I. Microaggregates and Microaggregate Blood Filters

Early blood bankers were aware of the formation of large clots in stored blood for which some type of filter was needed.[2,3] Later workers recognized that in addition stored blood contained "microaggregates" composed of dead granulocytes, platelet debris, and fibrin strands. The microaggregates (MA) were small, 20-120$\mu$, and since they were not felt to be harmful early blood filters were designed with pore sizes of 170-230$\mu$ to provide maximum flow rates.[4,5,6]

Swank showed that MA could be efficiently and safely removed by passing blood through a dacron wool filter.[7] Further, he showed that in patients on cardiopulmonary bypass, in whom the MA debris enters the arterial circuit directly, use of an in-line microaggregate blood filter (MABF) appeared to decrease the incidence of postoperative cerebral dysfunction.[8]

In 1970 Moseley and Doty[9] reported multiple pulmonary emboli of amorphous and cellular debris in two Vietnam soldiers who had died from respiratory insufficiency after receiving 97 and 27 units of blood respectively. Neither soldier had a direct pulmonary injury. This material stained PAS-positively and histologically was similar to the debris observed in banked blood. The implication of their paper was that microaggregates in the transfused blood which were not removed prior to infusion had played a role in the respiratory distress noted in these soldiers.

The exact role of microaggregates, however, in the formation of the adult respiratory distress syndrome has been difficult to determine. A direct physical obstruction of the pulmonary microvasculature by the microaggregate debris could theoretically produce this clinical picture. There may also be an indirect effect mediated by vasoactive materials such as serotonin released from the platelets contained in the emboli. Although either process, obstruction with distal infarction or release of chemical agents, can produce deterioration of gas exchange across the alveolar-capillary membrane, it is not clear if other factors such as hypotension are also playing a part in the development of pulmonary dysfunction. Indeed, other studies in similar patients have not found evidence that death from pulmonary failure following massive transfusion was consistently associated with micro-emboli from banked blood.[10,11]

Controversy over the need for special microaggregate blood filters continued through the early 1970's. Experimental data from animals supplied additional heat but little light to the debate. While some studies found definite changes attributable to microaggregates others failed to provide confirmatory data. A

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major criticism of these animal studies was that they used different species (dogs[12] and baboons[13]), and different experimental conditions hampering both comparisons between studies and extrapolation to man. Dog blood, for example, does not develop microaggregate debris to the same degree as human blood.[14] Similarly, an isolated perfused baboon lung would seem to bear little resemblance to the intact functioning human organ.

Human research supporting the use of MABF for prevention of the adult respiratory distress syndrome was provided by Reul and co-workers.[15] [16] They showed that acute trauma patients who received massive blood transfusion through a $40\mu$ MABF had a lower incidence of ARDS than did a control group of patients who received blood through a standard $170\mu$ filter. Reul's data, however, has been criticized for a lack of uniformity between the two groups of patients.[11] [17]

Reul's work does not address the question of benefit derived from the routine use of MABF for the infusion of lesser (1-10 units) amounts of banked blood and such volumes comprise well over 90% of all transfusions given. Industry thus far has developed a variety of MABF with pore sizes in the range of 20-40 microns. They are efficient and apparently do not harm needed blood components, but they are expensive. Since a MABF with attached administration set currently costs about $3 more than the standard $170\mu$ filter, evidence that a MABF is required for all of the 5 million units of blood estimated to be transfused yearly in the United States[18] would have obvious economic impact.

Several recent studies have provided additional information on the usefulness of MABF for low volume transfusions. Virgilio and co-workers[19] studied 40 patients undergoing aneurysmectomy and found postoperatively that there was no difference between a MABF ($40\mu$) group and a group receiving blood through a standard ($170\mu$) filter, with respect to pulmonary function, or laboratory tests of hemostasis. The transfusion volume in their study was 6.5-7 units. Takaori[20] and his group divided 16 patients having unspecified major abdominal surgery into two filter groups. They found some changes reflecting an increase in pulmonary dead space and concluded that diffuse MA embolization had occurred only in the standard ($170\mu$) filter group. However, they reported that the ventilatory function in their patients was well compensated and no signs of clinical pulmonary dysfunction was reported. Barrett et al.,[21] found that when over 20% of the blood volume was transfused as banked blood and a MABF not used, changes in intrapulmonary shunting occurred. No changes in blood gases were noted and no clinical evidence of respiratory distress was reported. Snyder et al.,[22] evaluated 40 patients undergoing elective total hip replacement. They found no changes in pulmonary function, hemostatic function or incidence of infection in either of two groups of patients who received between 4 and 4.5 units of blood through a $20\mu$ MABF (n=20) or a $260\mu$ large pore filter (n=20). Their study included a period of postoperative blood gas evaluation of 48 hours.

Although these studies failed to show a requirement for routine use of MABF in "healthy" patients there is no published data evaluating the benefit of MABF in patients with compromised pulmonary function due, for example, to lung carcinoma or pneumonia. Although there is little doubt that the MA are trapped by the lungs, in the quantity present in 1-7 units of blood (7-50 x $10^7$ particles)[23] they have yet to be shown clinically to cause significant harm to a normal human lung. Well controlled clinical studies on patients with compromised lung function are hard to perform, and equality between MABF and standard filter groups is mandatory if valid comparisons are to be made. It is possible, therefore, that the ability of a diseased lung to compensate for microemboli is impaired in such patients and routine use of MABF will be of value. Controlled human studies supporting this thesis, however, are currently lacking.

Pending further data the indications for use of MABF appear to be limited to patients receiving massive transfusions (10 or more units of blood), and patients transfused during cardiopulmonary bypass. Special microaggregate blood filters need not be used for patients receiving either washed or frozen-thawed red cells since the MA are removed during the washing procedure.[24] Further, these filters are not recommended for use with platelet or granulocyte concentrates as the filter may remove viable cellular elements.[25] [26] Neonates who are receiving blood less than three or four days old, probably do not need to receive microfiltered blood since such units contain fewer MA. However, here too, there are no controlled studies found in the literature.

### II. Compatibility of Intravenous Solutions

The rate at which a unit of blood can be infused is dependent in part on its hematocrit and thus on its viscosity. The hematocrit of a unit of whole blood is about 38%, while a unit of packed cells approaches 75%. As the viscosity of blood increases exponentially at hematocrit readings higher than 50%[27] a unit of packed cells will flow more sluggishly than will a unit of whole blood.

At the cornerstone of 1979 blood banking practice is the concept of component therapy which calls for the separation of platelet rich plasma from the donor whole blood unit and the storage of the remaining erythrocytes as packed red blood cells (PRBC). During surgery, where transfusion may be needed rapidly and in large quantities, some physicians add a crystalloid or colloid solution to the red blood cells to decrease viscosity.

The Standards of the American Association of Blood Banks state that only U.S.P. sodium chloride (0.9%) should be added to blood prior to or during transfusion.[28] Although other solutions could be added to PRBC to increase flow rates, there is a definite risk associated with the administration of blood simultaneously with certain types of intravenous solutions.

In 1950 Wilson[29] reported a hemolytic transfusion reaction after infusion of blood mixed with 5% dextrose in water. He showed that hemolysis occurred in vitro in the administration set. It was caused by the hypotonicity of the dextrose solution relative to normal plasma. This resulted in osmotic lysis of the red cells and the infusion of free hemoglobin and red cell stroma. Although free hemoglobin presents no clinical problems, and is indeed being evaluated for clinical use because of its favorable oxygen carrying properties, infusion of red cell stroma has been associated with acute tubular necrosis and renal failure.[30] Additionally, mixing blood with 5% dextrose in water can cause the red cells to aggregate and obstruct the flow of blood through the administration set.

Ryden[31] and Decesare et al.[32] have shown that when blood is mixed with 5% dextrose in water or 5% dextrose in 0.2% saline, hemolysis will occur in 30 minutes at either room temperature or 37°C. However, 0.9% saline, 5% dextrose in 0.4% saline or 5% dextrose in 0.9% saline will not produce hemolysis since the sodium concentration in these solutions are high enough to prevent osmotic lysis.

The use of lactated Ringer's solution, with a concentration of 3mEq/l of calcium, will not produce red cell lysis but will promote clotting in the unit of blood. The basis for the anticoagulant effect of the citrate in the CPD blood preservative lies in its ability to chelate calcium. The presence of free calcium is required for activation of several of the clotting proteins. Addition of lactated Ringer's solution to a unit of packed red cells, or merely using it to prime the intravenous tubing preparatory to starting a blood transfusion can result in the formation of small blood clots.[31] These clots, when infused, may lodge in the patient's lung posing an additional transfusion hazard. Since these reactions are more likely to occur when the solutions mentioned above are incubated with red cells at 37°C, such as occurs with the use of blood warmers,[31] even more attention need be paid to the compatibility of intravenous solutions when these devices are used.

Colloidal solutions are also used to dilute packed red blood cells. Aside from the increased risk of hepatitis, there are no contraindications associated with use of type-compatible fresh frozen plasma for the reconstitution of PRBC. Commercially prepared colloidal solutions, such as albumin and plasma protein fraction, can also be used in those situations where the clinical indications for the extra protein outweigh the extra cost of these products.

Rapid infusion of plasma protein fraction can be associated with hypotensive episodes[42 44] hence it should not be used if it is to be infused more rapidly than 10 ml/minute (vide infra). In situations requiring rapid infusion of blood, red cells can be reconstituted with one of the three crystalloid solutions mentioned above thus permitting any required plasma protein fraction to be infused at a slower rate. Many physicians do not find it at all necessary to reconstitute packed red cells, however, should clinical situations warrant such a practice, a compatible intravenous fluid must be chosen and properly administered.

### III. Blood Warming

The concept of routinely warming all transfused blood although controversial is strongly supported by some authors.[33] Blood is stored at a temperature between 1° and 6°C. Upon infusion of large volumes of cold blood, body temperature is lowered and a variety of physiological alterations occur depending on the temperature attained.

The greatest threat to life from hypothermia is the occurrence of ventricular fibrillation,[34] and the risk of developing this arrythymia increases as body temperature falls below 30°C. Hypothermia produces reflex vasoconstriction which is an attempt by the body to conserve heat. Further, a generalized showing of metabolic reactions occurs with a shift of the oxyhemoglobin dissociation curve to the left which decreases the availability of oxygen to already underperfused tissues.

When cold blood is infused into an antecubital vein or a central venous catheter, the first organ to be exposed to the sudden change in temperature is the heart. Boyan and Howland[35] documented the development of significant cardiac hypothermia by placing an esophageal thermocouple behind the cardiac atria during transfusion. Using this technique, esophageal temperatures of 20°C to 28°C were recorded on several occasions during massive transfusion.

In their evaluation of the effect of cold blood on the incidence of cardiac arrythymia they found that 21 cardiac arrests occurred in 36 patients (58%) receiving over 3000 ml of cold blood at rates of 50-100 ml/min, while in 45 patients receiving similar amounts of warm blood at equivalent rates, only one cardiac arrest (2%) was recorded.[36] These blood flow rates represent a minimum of one unit every 5-10 minutes for 30-60 minutes. With such massive transfusions the need for warmed blood is clear. The key word here is massive. There is no evidence that the routine warming of 1-2 units of blood administered over several hours is beneficial. Since it is unusual for large volumes of blood to be needed during most surgical procedures, and since a majority of the transfusions given by the medical service are low volume, there are few times when the use of a blood warmer is required. The majority of patients will tolerate infusion of cold banked blood without any apparent ill effects. Polesky has recently shown that the temperature of a unit of red blood cells hanging from an intravenous pole will approach that of the ambient air in less than one hour.[37] Although little harm is likely to result from the administration of properly warmed blood to a patient, transfusion of improperly warmed blood may be fatal.

There are several types of blood warmers currently available, and each has associated hazards. The simplest warming device is a long plastic coil designed to be placed in a pan of warm water at 37°C. This type of warmer is unreliable and overheating of the blood can easily occur. If the coil is placed in a container of too hot water the blood will literally be cooked. The resulting infusion of red cell stroma can prove lethal.

Electric blood warmers are available and have some type of visual and/or audible alarm to protect the red cells from overheating. Although usually reliable, they are expensive and may malfunction. Accordingly, such instruments should be subject to frequent quality control and constant temperature monitoring.

Microwave blood warmers were popular in the early 1970's. These devices worked well in theory but in practice were associated with temperature-induced hemolytic transfusion reactions.[38, 39] They are not in wide use today.

Use of blood warmers is indicated for the following situations:

1. patients receiving rapid and massive transfusions ( > 1 unit/10 min.).
2. exchange transfusions in neonates.
3. patients with pathological cold agglutinins reactive in vitro at 37°C.

Because of the potential hazards associated with improperly warmed blood, the use of blood warmers for low volume transfusions should be actively discouraged. The risk incurred by the routine and indiscriminate use of these devices far outweighs the benefit one might expect to gain from such a practice.

### IV. Hypotension and Plasma Protein Fraction

During the past several years, there has been an increase in the use of plasma protein fractions (PPF) for volume expansion. Currently marketed under a variety of trade names, Plasmatein®, Plasmanate®, Protenate®, and Plasmaplex®, PPF was first licensed by the FDA in 1958. Albumin comprises 83% of PPF, with the remainder of the product consisting of $\alpha$ and $\beta$ globulins.[40] Normal Serum Albumin (Human) must contain at least 96% albumin and having been subjected to a further purification step, is a more homogeneous product.[40] This additional processing is of some importance because the methods used to prepare albumin also remove vasoactive materials which are found in PPF.

The relationship between 5% plasma protein fraction and low blood pressure has been known since the early animal experiments with this product.[41] Few problems, however, were seen in man with routine intravenous administration until 1973 when Bland[42] reported hypotension following rapid intravenous infusion of PPF to patients undergoing cardiopulmonary bypass. A drop in blood pressure was noted when as little as 25 ml of the solution was administered.

Kallekrein and bradykinin were among the substances implicated by Bland's group as being the etiologic agents. Since the lung, a major site of bradykinin inactivation in man,[43] was excluded from the circulation during the bypass procedure, it was felt that bradykinin was the likely offender.

Following this report, one company modified its commercial processing of PPF to remove most of the bradykinin activity. Paradoxically, the result was an increase in the reported incidence of hypotension associated with this product.[40] Some light was shed on this enigma by Alving et al.,[44] who provided evidence that prekallekrein activator (PKA), in the form of Hageman-factor fragments, is responsible for the hypotension. They studied the lots of PPF implicated in the reported episodes of hypotension and found a better correlation between the PKA activity and hypotension than between the concentration of bradykinin and hypotension. PKA acts enzymatically on prekallekrein to generate bradykinin which in turn produces hypotension. The kallekrein system is inhibited by C1 inhibitor,[45] which occurs naturally in plasma. Failure to provide sufficient time for the C1 inhibitor to inactivate kallikrein may explain why the faster the rate of PPF infusion, the more frequent and severe the hypotensive reactions. Further, heating PPF to 60°C for 10 hours during commercial preparation destroys the C1 inhibitor without altering PKA activity.[45] PKA activity is rarely found in Normal Serum Albumin, correlating with the paucity of reported hypotensive reactions following use of this product.

The following represents current concepts with regard to use of PPF:

1. hypotension is associated with use of PPF.
2. hypotension is related to administration at rates greater than 10 ml/min.
3. hypotension is not related to a specific lot or manufacturer.

4. hypotension can be controlled by slowing the rate of infusion.
5. use of PPF is contraindicated in patients during cardio-pulmonary bypass.
6. PPF is to be administered intravenously and not via an arterial route.

Plasma protein fraction is a useful agent for the expansion of blood volume, however, it must be used with due regard for potential hypotensive episodes. In cases where rapid plasma expansion is needed Normal Serum Albumin, crystalloid or single donor plasma is indicated.

### V. Toxicity of Plasticizers

Polyvinyl chloride (PVC) was synthesized in 1931. Although this material is rigid, mixing it with another synthetic material called a plasticizer will impart flexibility to the polymer. In 1933 the plasticizer, Di-2-ethylhexylphthalate (DEHP) was synthesized, and the subsequent incorporation of DEHP and PVC led to the development of the PVC plastic storage bags in use today.

Strumia in 1955[46] studied the effect of PVC on the blood stored in such bags. Jaeger[47] and Hillman[48] showed that not only did the phthalate plasticizer leach into the blood, but high concentrations of DEHP could be found in tissues examined from transfused patients. This report prompted concern over the potential terato- and carcinogenic effect of DEHP.[49] The concern over DEHP is not limited to its presence in blood bags, for this chemical is ubiquitous, being routinely used in all types of medical and commercial plastic manufacture.[50] Indeed, in several studies untransfused control patients were found to have detectable levels of DEHP, presumably of environmental origin.[47] [52] The finding of organ levels of DEHP thus goes beyond hospitalized patients and becomes a problem for the healthy population as well.[51]

DEHP comprises up to 40% of the total weight of the PVC blood bag.[52] The rate at which it leaches into blood is in the range of 0.25 mg/dl blood/day at 4°C.[47] Levels of DEHP in the supernatant of platelet rich plasma stored at room termperature were very high, 44mg/100 ml after 72 hours.[53] Migration of the plasticizer into blood apparently requires the presence of lipoproteins. This conclusion is based on studies which showed that there was little DEHP in the CPD preservative prior to phlebotomy, none in saline stored in PVC bags, and in washed red cells stored in PVC bags the amount of plasticizer was only 4-6% of the total recorded for whole blood stored under the same conditions.[53]

Reviews of the toxicology of DEHP have failed to find any definite clinical evidence of adverse effects in man from use of this chemical in blood storage bags.[54] [55] Since this certainly does not mean that ill effects from the use of DEHP will never be found, a rational approach would seem to be to develop new plastics and plasticizers which will not migrate into blood. This will remove one more potential hazard associated with blood transfusion. The final chapter on the danger of plasticizer migration is yet to be written.

There are many complications associated with blood transfusion. It is imperative that the physician order the right blood component, for the right reason, in the right amount, and at the right time. Blood must never be considered a tonic; nor should it ever be withheld if truly needed. The proper use and administration of blood and blood products should be a goal for all physicians involved in patient care.

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# Post-Transfusion Hepatitis: A Continuing Problem

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### Introduction

The last decade has seen the identification of and development of testing procedures for both hepatitis A and hepatitis B viruses. Detailed knowledge of the sero-epidemiology of both these forms of hepatitis has evolved and this has increased our understanding of the nature of viral hepatitis to a remarkable degree. Yet, despite the availability of serological testing for hepatitis B on an almost routine basis, the incidence of post-transfusion hepatitis remains significantly high. It is the purpose of this review to outline the respective roles of the various viruses in the etiology of post-transfusion hepatitis and to summarize the clinical syndrome.

### Hepatitis B Virus

Screening of donor blood by the first generation tests for hepatitis B surface antigen (HBsAg) resulted in a significant reduction in the incidence of post-transfusion hepatitis;[1] this was further reduced by the institution of radio-immunoassay (RIA), a third generation test, in 1973.[2] Despite the routine screening for HBsAg, by RIA, however, hepatitis B-related post-transfusion hepatitis has not been eradicated. It has been shown that blood negative for HBsAg but positive for anti-HBc, can transmit the disease;[3] the relationship between HBsAg and anti-HBc is shown in the figure. It appears that blood from a donor recovering from hepatitis B infection may be infectious during the period that anti-HBc is present, but is less likely to be infectious once anti-HBs is detectable.[3] Screening blood for anti-HBc may thus be an alternative way of preventing the small number of hepatitis B related cases that occur. The question at issue is whether the expense involved in such an undertaking is justifiable, since the incidence of hepatitis B following transfusion with HBsAg negative blood was only 0.8% in the study of Alter[4] and furthermore, although anti-HBc is invariably present in the serum of chronic carriers, it may be absent early in acute hepatitis B[5] (see Figure). Further information on the cost and efficacy of anti-HBc testing should be obtained before a thorough appraisal of the role for anti-HBc testing on a wide scale can be made.

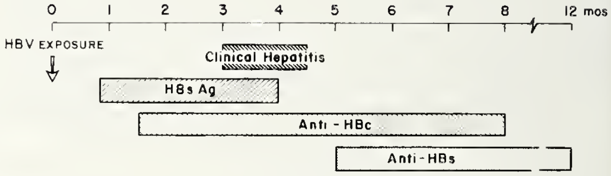

Figure 1

In contrast to the presence of anti-HBc, the presence in donor blood of anti-HBs, the neutralizing antibody in hepatitis B infection, is not indicative of infectiousness. There is no evidence implicating anti-HBs-positive blood in the etiology of post-transfusion hepatitis.

An additional risk factor in the development of post-transfusion hepatitis B has been the use of commercial, rather than voluntary, blood. The combined effect of the exclusion of commercial blood donors and of screening all blood donors for HBsAg at the National Institutes of Health resulted in 83% reduction in both total and icteric hepatitis.[6] Although it was impossible for the investigators to ascribe exactly the relative importance of each variable, they estimated that exclusion of the commercial donor was the more significant. In a study conducted in New Jersey by Goldfield et al.,[7] 4.7 recipients per 1,000 units of volunteer blood (13.7 per 1,000 recipients) and 8.7 recipients per 1,000 units of commercial blood (20 per 1,000 recipients) showed evidence of HBV infection. These units were all HBsAg-negative by radioimmunoassay. From these data it is clear that even fully tested commercial units continue to be associated with a higher incidence of hepatitis B virus-associated post-transfusion hepatitis. Goldfield et al.[7] have shown that 1.5 HBsAg-positive/1,000 volunteer donors and 5.4 HBsAg-positive/1,000 commercial donors existed; when these rates were compared with the frequencies of HBsAg-positive icteric hepatitis of 0.9/11,000 units of volunteer blood and 4.3/1,000 units of commercial blood, it is clear that radioimmunoassay screening for hepatitis B surface antigen does not reveal as many donors who are liable to transmit hepatitis as would be ideal. It is therefore clear that even third generation testing for hepatitis B surface antigen is not sufficient to eradicate hepatitis B-associated disease. Despite the fact that

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hepatitis B has not been eradicated by sensitive radioimmunoassay screening techniques, it is clear that hepatitis B constitutes only a small fraction of the overall cases of post-transfusion hepatitis. As will be discussed below, non-B hepatitis is the major culprit.

### Hepatitis A Virus and Other Identifiable Viruses

Since the discovery in 1973 by Feinstone and colleagues[8] of hepatitis A virus in the stool of a patient with short incubation viral hepatitis, a considerable amount has been learned about the sero-epidemiology of hepatitis A. One fact is that transient viraemia is associated with this infection. Many investigators have now shown[9-10] that hepatitis A is not a significant etiological factor in the causation of post-transfusion hepatitis. Cytomegalovirus, EB virus and other hepatotrophic viruses are also infrequent agents in the overall causation of post-transfusion hepatitis.[9 11] Sero-epidemiological studies of hepatitis A have shown that the major route of transmission of the infection is through the oral-fecal route, and because of the very short period of viremia, parenteral infection is unimportant. Hepatitis A infection can be diagnosed by looking for a serial rise in titer of anti-HA. This has been done and found negative in numerous studies of post-transfusion hepatitis; hence, hepatitis A is not a significant factor in the genesis of post-transfusion hepatitis.

### Non-A, Non-B Hepatitis

While hepatitis B is a relatively rare post-transfusion occurrence there has not been a significant reduction in the overall incidence of post-transfusion hepatitis. The frequency is currently of the order of 10%,[1-13] with up to 95% serologically unrelated to hepatitis A, B, cytomegalovirus or EB virus. This observation suggested very strongly the existence of one or more etiological agents responsible for post-transfusion hepatitis. As early as the 1950's, studies were done in which sera from six asymptomatic blood donors who had been implicated in the transmission of viral hepatitis were given to volunteers.[14] Serum from five of the six donors was available for retrospective testing. Two were HBsAg-positive, three were negative for hepatitis A and B yet all caused hepatitis in up to 47% of recipients. This provided strong evidence that a third type of human viral hepatitis, non-A, non-B hepatitis, existed, which was due to a transmissible agent. Additional studies[9 11] utilizing testing for hepatitis A, B cytomegalovirus and EB virus, have confirmed the finding that 60 to 90% of post-transfusion hepatitis is not caused by any of these agents. Further, like hepatitis B, there has been a strong correlation between the source of donor blood and the development of non-A, non-B hepatitis:[2] the frequency of non-A, non-B hepatitis is five[2] to ten[11] times more common after transfusion of commercial rather than volunteer blood. This provided more proof of the existence of an infectious agent transmitted by the donor. Additional evidence of the existence of a transmissible agent in non-A, non-B hepatitis has been presented recently[15 16] in which sera from patients with non-A, non-B post-transfusion hepatitis were inoculated into chimpanzees and produced hepatitis. It has thus become clear that the majority of cases of post-transfusion hepatitis are caused by a transmissible agent the nature of which has not been further clarified. One report has now been published[17] in which immunodiffusion assays between acute and convalescent sera, obtained from patients with non-A, non-B post-transfusion hepatitis, have shown a precipitin line. These investigators have designated the antigen hepatitis C antigen. This study, therefore, is not definitive but it does suggest that there may be more agents in the etiology of post-transfusion hepatitis. Confirmatory and more detailed studies need to be undertaken. This is, however, the first indication that there is an antigen different from hepatitis A and hepatitis B antigen which may be related to one of the causative agents of this disease. In addition, the finding of a virus-like particle in the liver of a chimpanzee with acute non-A, non-B hepatitis was recently reported.[18]

### Clinical Features of Non-A, Non-B Hepatitis

The incubation period for non-A, non-B hepatitis ranges from 18 to 89 days.[14] It thus appears to have an incubation period between that of hepatitis A and hepatitis B. Systemic features such as fever, myalgia, and headache are less common in non-A, non-B hepatitis than in hepatitis A; similarly, the duration of symptoms and degree of jaundice have been less in the cases of non-A, non-B hepatitis. Clinically, this form of hepatitis resembles hepatitis B more than it does hepatitis A. Probably of most significance, however, both from a point of view of the overall morbidity and from a public health standpoint, is the fact that chronic hepatitis, and presumably chronic viremia, is disturbingly common. Knodell et al.[19] documented chronic hepatitis in 10 out of 44 cases of acute non-A, non-B post-transfusion hepatitis. Eight of these 10 patients showed features of chronic active hepatitis on liver biopsy. Hoofnagle et al.[14] documented chronic hepatitis in 2 of 6 cases. In many respects, therefore, non-A, non-B hepatitis resembles hepatitis B. Thus far, however, the extrahepatic manifestations of hepatitis B, such as polyarteritis and glomerulonephritis, attributed to immune complex disease, have not been described in association with non-A, non-B hepatitis. There is very little information on the rate of secondary infection or of non-parenteral spread of non-A, non-B hepatitis, although some patients with non-A, non-B hepatitis have not received blood transfusions. A recent report[20] indicates that newborn infants of mothers who have acute non-A, non-B hepatitis during the last trimester of pregnancy, have a high incidence of transaminase elevations, suggesting that this form of hepatitis, like hepatitis B, is transmissible vertically.

In summary, it appears that non-A, non-B hepatitis is more usually an anicteric, mildly symptomatic disease, and in the majority of patients will remain undetected unless transaminase testing is done. However, the proclivity for producing chronic hepatitis is the most distressing, especially since the incidence of significant chronic hepatitis and cirrhosis, with portal hypertension, is not yet known. Of equal concern is the fact that this pool of patients, who may feel well, are possibly infectious for the duration that they carry the non-A, non-B hepatitis virus (or viruses) in liver or blood. Such patients, if they donate blood, would perpetuate this cycle unwittingly.

## Prospects for Control of Non-A, Non-B Hepatitis

A 10% incidence of post-transfusion hepatitis and a propensity for the development of chronic hepatitis, reported in up to 30% of cases, suggests that up to 2-3% of transfused individuals may develop chronic hepatitis. This is a significant risk factor and underlines the need for control of this infection. The recent description of a hepatitis C antigen is promising, in that it indicates that an infectious agent is identifiable; however, the presence of this antigen in patients before transfusion and in some untransfused patients may lessen the importance of this finding. Recognition of, and screening for, the virus(es) responsible for non-A, non-B post-transfusion hepatitis is still a project for the future.

Control of post-transfusion hepatitis at present hinges on careful use of blood products, particularly those high risk products obtained from pooled plasma, and substitution of paid donors by an all-volunteer blood donor pool. The effect of replacement of a commercial source of blood by voluntary donors is illustrated by the results of the VA collaborative study in which the original incidence of hepatitis was 20.8% when over 90% of the blood was commercial. After the number of commercial donors was reduced to 4% the incidence of hepatitis declined to 6.2%.

Studies of the effectiveness of immune serum globulin prophylaxis have shown that ISG, given preoperatively to cardiac surgery patients, reduced the total incidence of hepatitis and of icteric hepatitis and has also reduced the incidence of chronic hepatitis following acute non-A, non-B hepatitis.[19] The patients in these studies received on average in excess of 25 units of blood. Whether ISG prophylaxis is effective in preventing or reducing the incidence of hepatitis after smaller transfusions, and, more importantly, if given after transfusion, is unknown. Studies to investigate these questions are necessary.

In all, there is really only one effective way of reducing the incidence of post-transfusion hepatitis: recognition of the etiological agent(s) and development of a test, applicable universally, to screen for the infectious agent(s). Until such time, judicious use should be made of blood and blood products.

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# Treatment of Hemorrhagic Gastritis

DR. HASTINGS K. WRIGHT (Chief of General Surgery, Yale-New Haven Hospital): Massive upper intestinal bleeding develops in three of every thousand patients hospitalized in Connecticut. Approximately 60% of such patients are recovering from major surgery. Another 20% have suffered major head trauma. Another 10% are on high dose steroid or aspirin therapy. A final 10% have either burn sepsis or hepato-renal failure. One patient in eight who bleeds in one of the above clinical settings will do so from hemorrhagic gastritis.

Until recently, prophylaxis against hemorrhagic gastritis was unavailable. The only medical treatment was to stop offending drugs, transfuse as indicated, and refer those patients who bled massively to surgery for subtotal or total gastrectomy. The mortality rate following surgery for hemorrhagic gastritis approached 70% at the beginning of this decade in Connecticut. Fortunately, significant improvements in prophylaxis and intreatment of hemorrhagic gastritis have occurred since then, all based on our present understanding that gastric acid is necessary for its genesis.

In order to appreciate how much of a problem hemorrhagic gastritis is in 1978 in Connecticut, we have asked several hospitals to look at their experience with this condition since prophylaxis and treatment with intensive antacid therapy came into widespread use three years ago, and since the H2 blocker, cimetadine, came into use within the last year. We asked that cases of hemorrhagic gastritis be confirmed by endoscopy or surgery and that the bleeding be serious enough to require transfusion.

The Waterbury Hospital reports that it has had 14 endoscopy proven cases of hemorrhagic gastritis in the past three years, 13 of which responded to massive antacid therapy. I.V. cimetadine was added in three cases in 1978. Only one patient required subtotal gastrectomy. None died.

The Bridgeport Hospital diagnosed 25 cases from October 1975 through July 1978. Thirteen patients had postoperative sepsis, and another four major head injury. All were treated with antacids with I.V. cimetadine added in the last three cases in 1978. Only two failed to stop bleeding and required partial subtotal gastrectomy. Twelve patients died of the disease process contributing to the stress ulceration, but none died of hemorrhage itself.

St. Vincent's Hospital in Bridgeport saw 25 cases of hemorrhagic gastritis in a similar period. All were treated with antacids, and only three required surgery. All 25 survived.

The West Haven V.A. Hospital reports that it diagnosed only three cases of hemorrhagic gastritis in the last two years, all in alcoholics. All recovered on massive antacid therapy and cessation of alcohol intake.

These figures are impressive. While hemorrhagic gastritis is still here, the average 500-800 bed general hospital is seeing less than 10 cases a year now. Furthermore, medical treatment is now very effective. In addition, the finding of so few cases at each hospital in the past three years strongly suggests that prophylaxis is being used in patients at risk. Is prophylaxis being used routinely?

DR. EDWARD DUNN (Chief of Surgery, Waterbury Hospital): Not every patient in our intensive care unit who is at risk for hemorrhagic gastritis is put on prophylaxis. However, the vast majority of them are, particularly if they develop a positive nasogastric aspirate while in the intensive care unit. We immediately put such patients on antacid therapy without endoscopy when this occurs and all of them to date have stopped bleeding. In my opinion, early erosive gastritis usually gives clear warning with bouts of small bleeds before massive bleeding occurs. Now, the types of patients who are routinely put on antacids without evidence of any blood in the nasogastric aspirate are: 1) all patients with sepsis, 2) all patients in shock, 3) all patients with multiple trauma, and 4) all elderly patients who have undergone protracted surgery, particularly for malignancies. We do not have the severe burns or open heart surgery that Yale and Bridgeport have. In addition, all the neurosurgical patients are on prophylaxis.

DR. WRIGHT: Now what do you mean by prophylaxis?

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*A Panel Discussion at Surgical Grand Rounds, Yale-New Haven Hospital, November 11, 1978.*

DR. DUNN: The greatest contribution to the prevention of stress bleeding is the use of pH paper to test the pH of the nasogastric aspirate. We check the pH hourly and bring the pH up to 5.5 to 6 using antacids. The nurses in the intensive care unit do this for us and titrate the amount of antacid necessary to bring the pH up to that range. Some of the patients require huge amounts of antacid, up to 100 cc per hour. For the past few months, we have been using cimetadine as well.

DR. WRIGHT: Dr. Panettieri, you've got major burns and open heart surgery at Bridgeport. What are you doing prophylactically with these patients?

DR. ANDREW PANETTIERI (Chief of Surgery, Bridgeport Hospital): We have put all patients with major burns on antacids since starting our burn unit four years ago, and have not had one episode of hemorrhagic gastritis in any burn patient in that period of time. Patients with burns under 20% are not placed on prophylaxis. We use the same type of prophylaxis as described by Dr. Dunn, and are starting to use monitoring of pH.

I think that it should also be pointed out that a lot of the patients who bled at the Bridgeport Hospital were not on the surgical service. Indeed, 9 of the 25 patients were on the medical service and had either renal failure or respiratory failure with sepsis. None of these patients was on prophylaxis either with cimetadine or antacids.

DR. RICHARD GUSBERG (Chief of Vascular Surgery, West Haven V.A. Hospital): I would like to reinforce what Dr. Dunn said about prophylaxis against stress gastritis. As the Brooke Army Burn Unit has shown, patients with over 35% whole body burns routinely show evidence of gastritis on endoscopy. If such endoscopies could be done on other patients who sustain severe stress, I think we would have evidence of a similar rate of gastritis. The vast majority of patients obviously have only small bleeds, and require neither transfusion nor operation. However, these patients should be given intensive prophylaxis, as has been reported recently to be highly successful in a randomized study of antacid prophylaxis in critically ill patients by Hastings and Skillman et al.[1] Another recent report on prophylaxis in head injury patients was presented by Halloran this year at the Surgical Forum.[2] He showed that patients who were randomized either to a placebo group or to a group getting prophylactic cimetadine 300 mg. every six hours had significant different rates of bleeding. Only one of nine patients receiving cimetadine showed any evidence of bleeding whereas seven of the eight patients receiving the placebo had evidence of bleeding. At the Veterans' Hospital, we have been very aggressive in using antacid prophylaxis therapy on all patients who develop sepsis after surgery. As our records demonstrate, we have not seen any evidence of post-operative hemorrhagic gastritis in the last two years with this prophylactic regimen. Theoretically, it is important to titrate the acid in the stomach by measuring the pH, but the nurses report that it is sometimes cumbersome and often we just end up giving standard doses of antacid therapy (approximately 60 cc per hour through the nasogastric tube).

In many centers, including the V.A. Hospital, cimetadine is being used empirically in patients who are at risk for the development of hemorrhagic gastritis in doses of 300 mg every six hours continuing for approximately 48 hours after resolution of the problem making the patient susceptible to hemorrhagic gastritis. Though no definite conclusions can yet be drawn about the efficacy of this regime, it should be noted that an intensive antacid regime alone is highly effective. In addition, there is no evidence that the combined use of cimetadine and antacid therapy will significantly improve on the excellent result achieved with antacid alone.

DR. WRIGHT: I wish now to turn our attention to the patient who comes to the hospital massively bleeding, or the patient who develops massive bleeding requiring transfusion. The time for prophylaxis is past. What do we do once we have proven endoscopically that the patient has diffuse erosive gastritis?

DR. MICHAEL DEAN (Chief of General Surgery, St. Vincent's Hospital, Bridgeport): It is very important that the endoscopist who is looking at the stomach in such patients be very experienced, since evidence from the Nottingham Hospital in Britain shows that different endoscopists agree only 65% of the time on the diagnosis of hemorrhagic gastritis. Our routine is to pass a large nasogastric tube and to lavage the stomach with chilled saline until visualization is possible with the endoscope and a diagnosis can be made. We then treat all such patients medically with both antacids as described by Dr. Dunn and in the last six months with intravenous cimetadine. We, of course, have no evidence at the present time that the use of cimetadine is additive to the use of intensive antacid therapy. Fortunately, our data shows that only 2 patients have had to go to surgery out of the last 25 so treated. In every case we, of course, also treated the underlying cause of the stress such as burn sepsis or sepsis following major intra-abdominal surgery as well as giving antacid therapy.

When should these patients be taken to surgery? We usually take patients with single-lesion-causes of massive upper intestinal bleeding like gastric ulcer or duodenal ulcer to surgery after they have essentially lost one blood volume—say 7-8 units of blood for an average adult male. Now we are beginning to think that we should go further in treating patients medically with hemorrhagic gastritis. I am not ready to give a numerical figure, but I would not stop medical therapy at 6-8 units if I were at the same time making progress in treating the primary cause of the stress.

DR. PANETTIERI: I would agree with Dr. Dean on this. We should try to avoid surgery if at all possible. None of us really knows what surgical procedure is best for this condition in an emergency. Everything has been recommended from vagotomy and pyloroplasty to total gastrectomy. When this happens, there is the clear suggestion that none of the operations proposed is better than any other. Certainly vagotomy and pyloroplasty gives the lowest mortality rate, but also gives the highest recurrence of rebleeding in the patients if the primary cause of the stress cannot be controlled.

DR. DUNN: I was intrigued by Dr. William Waddell's work in the 1960's which reported a high degree of surgical success of arresting bleeding and not having it recur with vagotomy and antrectomy. However, I must say that we have not performed this operation at the Waterbury Hospital in the last three years. Now, with the use of intravenous cimetadine, I think that we can probably do lesser procedures. We are all doing so little surgery for erosive gastritis in 1978 in Connecticut that it might be very difficult to determine by a prospective randomized study which operation is going to be the best and the safest procedure now that we have cimetadine. Again, in my own mind, in 1979 we ought to be trying the lesser operations first.

DR. GUSBERG: We are talking about mortality rates after surgery, but I think that it is important to emphasize that the primary disease causing the hemorrhagic gastritis is probably going to be the ultimate factor in determining the patient's course and mortality rate. Indeed, the study from the Beth Israel Hospital shows that 21% of the patients receiving antacid titration died as compared with 14% who were not receiving prophylaxis in this randomized trial. The patients on prophylaxis died of the cause of the stress, not the hemorrhage.

It is not yet apparent what operation will be the preferred operation in the 1980's for hemorrhagic gastritis. In my own opinion, if a patient requires surgery who has been on a drug such as aspirin or alcohol, I would be inclined to do a lesser procedure such as a vagotomy and a pyloroplasty. However, if the patient was bleeding in the presence of uncontrolled sepsis or major trauma, I would consider doing a subtotal gastrectomy and vagotomy. I think one probably has to tailor the operation to the amount of stress in the patient. It is also important to emphasize vagotomy as part of any procedure done for hemorrhagic gastritis.

DR. WRIGHT: There is also a new procedure which has recently been described by Dr. Aust from San Antonio,[3] in which simple four-vessel ligation of the right and left gastric arteries, and the right and left gastro-epiploic arteries is performed without an incision being made in the stomach. Aust operated on severely ill patients with a diagnosis of hemorrhagic gastritis made endoscopically and had only 2 of 21 severely ill patients rebleed. Has anyone on the panel had experience with this operation?

DR. DEAN: One of the patients down at St. Vincent's had such an operation and did not rebleed.

DR. WRIGHT: We have done the operation four times at Yale with no rebleeds. Are there any questions from the audience?

*Question:* I would like to report a case rather than ask a question! We treated one young patient who developed an obstruction of the stomach when given large doses of aluminum hydroxide in the prophylaxis of hemorrhagic gastritis. This patient was given 100 cc. of aluminum hydroxide per hour and there had been no pH monitoring. This was probably an excessive amount of antacid administration, and I believe that we should all go to pH monitoring in order to reduce the amount of antacid delivered to that necessary to bring the pH up to 5 or 6.

*Question:* Are there serious side effects from the use of cimetadine in the acute situation?

DR. WRIGHT: As you know, cimetadine has low toxicity in the treatment of peptic ulcer and related diseases when used for less than eight weeks. I am aware of no studies of side effects in the acute situation except for anecdotal reports that mental confusion and coma have occurred, especially in elderly patients with serious underlying disease who are on higher than recommended doses of cimetadine and who also have impaired renal function. These side effects also include headache, dizziness, fatigue, diarrhea, muscular pain, constipation, etc., but a similar frequency of these perhaps non-specific side effects has also been noted in placebo treated patients in chronic studies. Certainly, at the present time, when treating hemorrhagic gastritis we need not exceed the 300 mg. per 6 hour I.V. dose which has been recommended.

I would like to thank particularly the surgical residents at the several hospitals who did the data gathering for this study, and I would like to thank both the panel and the audience for this stimulating discussion.

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# The Individual Practice Association Comes to Connecticut: Connecticut's First IPA—HMO

ROBERT W. DOERING, M.D.

If one were to ask, "What's new in Connecticut Medicine?", one answer would be Connecticut's first operational *Individual Practice Association* (I.P.A.), Greater Bridgeport Medical Foundation, Inc. Its formation, together with the Foundation's development of Connecticut's first comprehensive prepaid health plan designed entirely by practicing physicians, represents a landmark in Connecticut medicine.

In the December 1977 issue of *Connecticut Medicine,* Walsh McDermott, M.D., in an article entitled, "The Future of General Medical Care," speaks of "another way . . . of meeting national goals of general medical care for everybody, is through Foundation's for Medical Care." After a brief description, he goes on to say," . . . it is a way of handling both the expertise and access problem and still keeping people in the private sector. I hope it gets a thorough trial."

With that introduction, this article will focus on a concept of medical practice new to Connecticut physicians, the Independent Practice Association (I.P.A.), its development in Bridgeport and its new comprehensive Health Maintenance Organization (HMO), Physicians Health Services (PHS).

The I.P.A. is unique in that it permits a member physician to practice medicine from his office on a fee-for-service basis while offering professional services on a prepaid basis to patients who enroll in the IPA's health maintenance organization.

The development of this concept by a group of Bridgeport doctors has evoked physician interest throughout Connecticut. It should be noted that an IPA has also been developed by physicians in New Haven County and has recently become operational.

## Origins

One type of IPA is known as a Foundation for Medical Care (FMC). It is usually sponsored by a local medical society to serve two functions: to develop a prepaid health insurance program and to carry out peer review on the quality of health care.

Greater Bridgeport Medical Foundation, (GBMF) had its roots in the San Joaquin California Medical Foundation formed twenty-four years ago. The stimulus to the formation of San Joaquin's Medical Foundation was the potential threat to local physicians of losing patients to the Kaiser Health Care System planning to locate in the area, using prepaid group practice physicians practicing from a central location.

As a positive alternative, the San Joaquin medical society responded with the first prepaid health plan to offer virtually complete medical care to its subscribers for a fixed monthly premium, while still allowing enrolled members to see their local community physician. The San Joaquin Foundation was so successful that Kaiser could not compete effectively and failed to become operational in the area.

In 1975 a similar situation arose in Bridgeport, where a salaried, staff-model Health Maintenance Organization (HMO) made its appearance. This was viewed by local physicians as a threat to the existing practice of medicine. In this case, a group of Bridgeport consumers had secured a series of federal government grants to establish a staff-model Health Maintenance Organization (HMO) for Bridgeport. A local physician was hired as a medical director to recruit local physicians to form a multi-specialty group practice of salaried physicians to practice from one medical facility in direct competion with local practitioners. The prospect of patient requests for

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ROBERT W. DOERING, M.D., a practicing internist for the past 25 years in Bridgeport, has been the president of Greater Bridgeport Medical Foundation, Inc. since the IPA—HMO began developing in 1975. The program is marketed in the Bridgeport area as "Physicians Health Services" and is generally referred to as PHS.

transfer of medical records to the salaried staff group had a remarkable focusing effect upon physician initiative.

The search for a positive answer to the challenge posed by the local closed-panel model HMO began with the author of this article. Robert W. Doering, M.D., served as a member of a special committee of the Fairfield County Medical Association to evaluate the feasibility of an I.P.A.-HMO of the medical foundation type. Later as president of the Greater Bridgeport Medical Association, Dr. Doering personally visited the San Joaquin Foundation for Medical Care, the Sacramento Foundation and the San Diego Foundation, all of which were successfully operating in California. From these visits basic information was obtained for initiating a Foundation for Medical Care of the I.P.A. type in Bridgeport.

### Determining IPA Feasibility

The next step was to invite Richard H. Egdahl, M.D., M.P.H. of Boston to speak to the medical staffs of the three Bridgeport Hospitals. In addition to being Director of the Health Policy Institute of Boston University and an accomplished surgeon, he was selected because of his broad knowledge of I.P.A.'s. Dr. Egdahl succeeded in generating a strong interest in Bridgeport physicians to pursue the feasibility of establishing an IPA for Bridgeport based on the following premises:

(1) To preserve the free choice for patient and physician and the doctor-patient relationship in a private practice setting.

(2) To develop a comprehensive benefit package designed specifically for the Bridgeport area.

(3) To offer a health plan on a prepaid basis for a specific monthly premium that would virtually eliminate additional out-of-pocket expenses for enrollees.

(4) To enlist the support of the majority of practicing physicians to participate actively in offering the IPA program to the greater Bridgeport area and to monitor health services through appropriate peer review at the local level.

(5) To allow physicians to participate in the IPA program while continuing the practice of fee-for-service medicine.

(6) To maintain the decision making for health care delivery at the local level in the hands of practicing physicians.

(7) To enable local private practitioners to provide a positive alternative for health care delivery totally within the private sector to compete with the staff-model (closed panel) HMO.

### IPA Development

The next step was to determine if local physicians were prepared to take steps to form a new organization. In view of the fact that there was no provision within the structure of the Greater Bridgeport Medical Association for a system of health care delivery, the feasibility of forming a separate new organization was considered. An IPA could provide a management system for health care delivery. It would utilize a staff specifically trained to administer the prepaid health plan and be exclusively responsible to local physician leadership. It would provide an effective interface with hospitals, insurance companies, and health agencies. Moreover, it would have the collective voice of several hundred physicians rather than fragmented efforts of solo practitioners.

In August, 1975, 21 Bridgeport physician members of the Greater Bridgeport Medical Association chartered a bus and journeyed to Boston to spend a day with Dr. Egdahl and his staff. Specific recommendations were outlined to initiate development of a prepaid health plan, gain physician support, plan for peer review, and to study the legal requirements for incorporation. It was agreed to hire this group of experts from Boston University to be our consultants in organizing an I.P.A.

The new organization next received the approval of the Board of Trustees of the Greater Bridgeport Medical Association to be its sponsor for presentation to the local community of practicing physicians.

A vigorous campaign was then launched to get physicians informed and actively involved in the Greater Bridgeport Medical Foundation.

Informative talks to familiarize Bridgeport physicians with IPA concepts and organization were held at staff meetings of the three Bridgeport hospitals as well as all specialty sections within the hospitals. A monthly newsletter was published to update doctors on our progress.

It became apparent at the outset that physician involvement would be the key factor in the success of the IPA.

The original nucleus of 21 physicians steadily gained support from their peers until today, 280 physicians representing more than 70% of the private practicing physicians, have signed individual contracts as PHS participating physicians. This number represents a significantly larger number of participating physicians than Blue Cross & Blue Shield of Connecticut has in the Bridgeport area at the present time. It is also significant that many of our current participating physicians were originally opposed to the whole idea.

### Financial and Management Support

Our next task was to secure financial support of GBMF. It was felt that a financial contribution by each member physician would be a meaningful demonstration of personal commitment. Each participating physician, whether solo practitioner or member of a group, donated $500 out of his pocket to finance the initial organization and staffing of the organization. Over $130,000 was raised in this manner so that by September 1, 1977, the Greater Bridgeport Medical Foundation became the first IPA-type HMO exclusively funded by physicians to become operational on the East coast. This type of initial funding was done to insure exclusive physician control of policy determination for the organization. The next step was selection of our executive director. The first executive director served for five months before replacement by our current executive director, Michael E. Herbert, whose qualifications include graduation from Harvard's Business School and completion of a special training program for Health Maintenance Organization Managers as a Wharton School Fellow at the University of Pennsylvania. He also brought to GBMF six years of research and management analysis on HMO's of both the "closed panel" (prepaid group practice) and the "open panel" (individual practice association) variety while working with Paul M. Ellwood, Jr., M.D., a prominent leader and authority on health care delivery.

### GBMF Organization Format

Greater Bridgeport Medical Foundation, Inc. became approved and registered by the Connecticut State Insurance Department as a private, non-profit corporation, with permission to offer our prepaid comprehensive benefit package called Physicians Health Services (PHS). It is also officially approved by the Connecticut State Dept of Health as a Health Maintenance Organization of the I.P.A. type.

The GBMF's Board of Trustees provides for 33 directors. Of these "seats," 21 are presently occupied by physicians and one by a dentist, with the remaining seats reserved for individual subscribers who are actually enrolled in our health plan.

The terms of one-third of the directors of the Board of Trustees expire annually, permitting both continuity and turnover on the Board. Five officers are also elected to serve on an annual basis.

### Service Area

GBMF offers its health plan through employer groups and labor organizations with employees or labor union members who live or work in the greater Bridgeport communities of Bridgeport, Fairfield, Stratford, Trumbull, Monroe, Easton and Huntington.

### Community Involvement in PHS

GBMF recognizes the need for a broad base of community involvement to structure health care delivery to meet local health needs. Physicians Health Services represents the combined efforts of various groups within the private sector working together toward a common goal.

Patients (now termed consumers) are involved not only as subscribers to PHS, but also serve on our Board of Trustees.

Industry and labor actively participate by offering PHS to their employees or members. Both groups help formulate policy by representation on the Board of Trustees.

The three local hospitals participate through contracts to provide hospital services and the three hospital administrators have all served as members of the Board of Trustees.

Ten medical laboratories also each have contracts to provide diagnostic services to PHS enrolees.

Two separate health insurance organizations provide integral services to PHS. Connecticut Blue Cross and Connecticut Medical Services (now consolidated as Blue Cross and Blue Shield of Connecticut) underwrite the hospitalization and major medical portions of the PHS contract with subscribers, and assist PHS in performing marketing, group billing and hospital and major medical claims administration. Because of their support of the IPA-HMO concept and its potential impact on health care in Connecticut, Blue Cross and Blue Shield have advanced a sum of $50,000 in the form of a non-interest bearing loan during GBMF's projected budget deficit period. The marketing program provided by Blue Cross and Blue Shield of Conn. will be described separately.

Physicians Health Services also contracts with Employers Mutual Insurance of Wausau for a computerized management information and claims processing system utilizing direct claim billing to Wausau via teletype.

### Marketing

GBMF has contracted with Blue Cross and Blue Shield of Conn. to market Physicians Health Services. A full time enrollment specialist, Hans V. Holt, has been provided by Blue Cross and Blue Shield and he markets PHS exclusively. He coordinates his efforts with regular Blue Cross and Blue Shield enrollment representatives. Together they market PHS to employers groups and labor organizations on an individually optional basis. GBMF expects to achieve its enrollment projections by utilizing Blue Cross and Blue Shield of Conn. marketing personnel, thereby capitalizing on their considerable experience and marketing penetration in Connecticut.

GBMF expects to employ its own marketing staff in the future as it grows and is able to absorb the additional administrative expense of its own marketing program.

### Participating Physician Agreements

With Physicians Health Services, the subscribing member obtains all covered health care services through participating providers. The professional services of non-participating providers are not covered except by referral with prior GBMF approval by a participating provider, except in emergency situations.

Subscribing members are informed of this arrangement at the time of enrollment in order to control both the cost and the quality of these services. Subscribers also select their primary care physicians to provide or arrange for the medical needs of the member and his family. A member is allowed to change physicians at any time, providing he is a participating physician.

Each of the 280 participating physicians have signed individual contracts to provide medical services to eligible enrollees. These physicians must accept the PHS fee schedule as their full payment for a twelve month period. These physicians also agree to participate in peer review activities regarding matters of quality, utilization and cost. Each physician agrees to submit a claim form to PHS for services performed. Physicians also agree to serve on GBMF membership, Professional standards, finance or claims review committees to establish IPA policy.

### Physician Reimbursement

Utilizing a large physicians' committee representing every participating specialty and sub-specialty group of physicians in the Bridgeport area, GBMF developed a reimbursement for services on a fee-for-service basis according to a set of fees mutually agreed upon by each specialty. Our mode of compensation was designed to operate with extreme simplicity so it could be administered by a small staff at minimal expense to GBMF. Instead of billing a PHS subscriber for an office visit or an operation, the doctor bills the plan, which in turn reimburses him out of the general subscription income. By billing GBMF according to their usual fees, individual physicians will have their fee profiles computerized to determine the reasonableness of GBMF's reinbursement during the initial operational period, and also to determine the appropriate reimbursement arrangement for future years. This fee schedule mode of compensation can also be used by GBMF as an accurate basis of operational cost predictability to relate to premium rates.

### Physician Risk Sharing

To assure fiscal viability for PHS during its first year of operation, physicians demonstrated beyond any doubt their total commitment to the IPA concept by their participation in risk sharing. Participating physicians actually assumed financial responsibility for the cost of services they rendered.

A unique reimbursement formula developed by GBMF is presently in effect. Twenty percent of the reimbursement fee for participating physicians is withheld until the end of a year's operation. Ten percent of the fee is utilized to defray the cost of processing claims, while the remaining ten percent is withheld to cushion the costs of any unanticipated claims exceeding premium income. If the reverse is true and a surplus exists in the risk account that exceeds the 20% of retained physician payments at the end of one year, the accrued savings can be utilized by distribution to participating physicians, to increase health care benefits or minimize premium increases.

The rationale of this concept rests in the fact that during the first few years, very few, if any, physicians will have more than 5% of their practice consist of PHS enrollees. Thus if only 5% of the physicians total revenues are generated from PHS, GBMF, by contract, will pay 80% of that 5% as reimbursement. This leaves only 20% of that 5% at risk. 20% of 5%= only 1%. Therefore it is unlikely that more than 1% of a physician's practice income will be at risk in PHS during the initial trial period. This concept also gives physicians a collective stake in keeping overall costs in line as all physicians are "at risk" for a portion of their fees.

### Comprehensive Benefits

The most significant impact of PHS on the Bridgeport area lies in its covered health services when these services are compared to traditional health insurance plans. Increasing the range of covered ambulatory services results in removal of incentives to hospitalize. Increased services are coupled with education efforts directed at both participating physicians and subscribers regarding appropriate indications for hospitalization and hospital emergency room use. These activities result in a significant reduction in utilization of expensive hospital services which in turn, provides PHS with an effective mechanism to keep premiums competitive with existing health insurance plans as well as the local staff-model HMO.

PHS provides full payment for visits to the doctor's office, including immunizations, physical examinations and out-patient diagnostic services including laboratory tests and x-rays. Full coverage is provided for in-patient medical and surgical services, hospital semi-private accommodations, anesthesia, plus laboratory and x-ray procedures. A minimal $10.00 co-payment is assessed for comprehensive adult physical exams, and a $15.00 co-payment is assessed for hospital emergency room usage. The latter is waived if the patient is admitted as an in-patient.

Provisions have been included for maternity benefits, rehabilitation care, treatment of alcoholism, as well as certain other specific disorders and coverage as spelled out in detail in the subscriber's group health contract.

A major medical policy provides additional coverages including psychiatric benefits and delineation of other specific benefits.

### PHS Claims Forms

Special claims forms for each medical specialty were developed to simplify claims processing. Once the most common services and diagnoses were identified, those appropriate for each specialty were printed on each specialty's claim form. Numeric coding permitted easy transmittal of essential data with a computerized management information system.

This extremely efficient claims processing system enables once full-time terminal operator to handle claims for approximately 5000 enrollees.

A key advantage of this form is that no signature of the PHS subscriber is required. A PHS member simply shows his PHS identification card at the time a medical service is received. The office staff supplies the name, address and PHS identification number to the claims form. The physician checks off the type of service rendered by code number on one side, the diagnosis by code number on the other side, puts down his usual and customary fee, signs his name and the claims form is ready for mailing! The physician's cash flow is accelerated by PHS's rapid computerized payment since no delay is entailed in requiring the patient's signature.

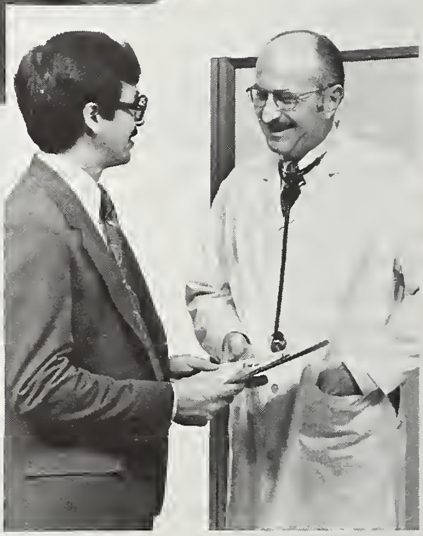
In summary, it can be stated that a new concept in health care delivery has arrived in Connecticut in the form of an independent practice association (IPA). This IPA is known as Greater Bridgeport Medical Foundation, Inc. (GBMF). This article of necessity only provides a very limited presentation of the foundation's initial development and operation. A comprehensive prepaid health plan called Physicians Health Services (PHS) has been developed entirely within the private sector of the free enterprise system. PHS utilizes existing providers and facilities—physicians, hospitals, medical laboratories, private insurance companies and doctors offices to offer comprehensive medical care of good quality on a cost efficient basis. PHS became operational on $150,000, a small fraction of the start-up costs required by the local salaried staff-model HMO in Bridgeport. PHS shifts the emphasis of health care delivery from the hospital to the ambulatory care setting without requiring expensive construction of a new group practice facility. The individual employee who enrolls in Physicians Health Services receives more comprehensive care coverage than has been available to him before (from traditional health insurance). This coverage is provided to him for a reasonable premium and he is assured of almost no costly out-of-pocket payments for medical care. The PHS enrollee almost never sees a medical bill.

The community benefits through a head-on competition within the free enterprise system between a staff-model HMO composed of a group of salaried physicians practicing from a single location and 280 private practitioners offering their services from their offices conveniently throughout the greater Bridgeport area.

Physicians Health Services basically differs from Connecticut Health Care Plan (CHCP) in New Haven, or the Connecticut Health Plan (CHP) in Bridgeport, or the North Central Conn. HMO of Windsor Locks. These organizations are closed-panel HMO's, also known as salaried, staff-model HMO's in which multi-specialty groups practice out of a single location. Physicians receive salary or have shared compensation arrangements unrelated to fees for their professional services. Contrast their with GBMF's Physicians Health Services (PHS), where 280 physicians treat PHS members in their own private offices with their other patients. A key difference between the closed-panel HMO's and PHS is that with PHS medicine continues to be delivered on a fee-for-service basis with physician income received in direct proportion to professional services rendered. No such direct correlation between services and income exists with the closed-panel HMO's.

Bridgeport physicians have demonstrated that in the comparatively brief period of two years a new dimension can be added to the private practice of medicine that is more acceptable and less disruptive to the physician community than the staff-model HMO. Since physicians determine where 85% of the health care dollar is spent, the logical conclusion is that the physician should control the destiny of health care delivery. Who can better determine the needs of the patient and the health care needs of the community than the physician?

It has been said that all the forces in the world are not as powerful as an idea whose time has come. We believe the IPA concept is such an idea, representing the best aspects of our present medical care system by preserving the physician-patient relationships, preserving fee-for-service medicine entirely within the private sector through physicians held accountable to their peers.



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# PSROs: Status Report

*The following is a report prepared by the Council on Medical Service of the AMA and accepted by the AMA House of Delegates at its November-December Convention in 1978.*

### PSRO Program Status

As of September, 1978, the Department of Health, Education, and Welfare had approved contracts for 182 conditional PSROs and 11 planning PSROs. After four years of litigation and regulatory complications, Texas was awarded a planning contract for a statewide PSRO. Only one area in Illinois, which is awaiting area redesignation, and the State of Nebraska are without a PSRO. It appears likely that only Nebraska will fail to generate local, physician-sponsored PSRO activity.

The fiscal year 1979 Department of Health, Education, and Welfare appropriation bill passed by Congress on October 15, 1978 contained $150 million for support of the PSRO program. For the first time Congress limited PSRO funding through the Medicare Trust Fund to $85 million, providing the additional $65 million from general revenues. The $150 million appropriation represented only half of DHEW's original budget request, and $24 million less than the President's request. The fiscal year 1979 PSRO budget will have the effect of requiring PSROs to reduce their average costs per case of review by approximately thirty percent.

### PSRO Program Evaluations

The fiscal year 1979 reduced level of funding reflects the continued doubts about PSRO program effectiveness expressed by Congress and the Administration's Office of Management and Budget. For example, in June, 1978, the U.S. House of Representatives Committee on Ways and Means, Subcommittee on Oversight held hearings on the PSRO program. Subcommittee Chairman Gibbons indicated that his Subcommittee would not allow the PSRO program to continue in its present form unless proven efficient, and cost-effective.

The Subcommittee heard the General Accounting Office (GAO) report of attempts to validate PSRO claims of savings in Medicare and Medicaid costs and days of care. The GAO study failed to substantiate a large portion of the PSRO claims, and discounted earlier reports of PSRO impact as having been based on incomplete or erroneous data and analyses.

Conversely, the recent 1978 DHEW/PSRO Evaluation reported that PSROs have reduced Medicare hospital utilization relative to non-PSRO areas. The report concluded that the program's concurrent review activity pays for itself.

An additional DHEW evaluation of Medical Care Evaluation Studies (MCEs) is expected to be completed by mid-1979. Preliminary results of this evaluation of the major quality assurance component of the PSRO program suggest that MCEs influence patterns of medical practice, by reducing those practices which deviate from locally accepted criteria.

### PSRO Plans for Fiscal Year 1979

Due to fiscal constraints and intensifying pressure for the PSRO program to demonstrate cost-effectiveness, DHEW has moved steadily to modify the program. Included in the Department's efforts are: (1) plans to focus PSRO review on suspected or documented problem areas, instead of screening or reviewing 100% of admissions; (2) plans to convert all PSROs from contract to a grant system of funding, to allow PSROs greater flexibility in allocating limited financial resources; (3) plans to lessen pressure on PSROs to perform additional types of review, e.g., outpatient department, ancillary services, ambulatory care, etc.; and (4) plans to "weed-out" PSROs which have substantial, uncorrected deficiencies.

The fiscal limitations also seriously affect the planned expansion of PSRO long-term care review. Long-term care review is funded through the administrative portion of the PSRO budget (the $65 million derived from general revenues). Since Congress has held the appropriations to 1978 levels, only 53 PSROs will be funded to perform long-term care review in FY 1979.

1979 is expected to be another year of political and financial uncertainty for the PSRO program. If the program is funded for fiscal year 1980, what major goals and objectives will be determined for PSRO? Will the PSRO mandate shift exclusively to cost-containment, or will the quality assurance be a primary program objective? In light of current federal priorities, the Council on Medical Service has discussed the current and future ability of the PSRO program to ensure quality of care. Should medicine be developing or refining alternative approaches to quality assurance? After hearing presentations on this subject, and on the status of quality assessment techniques, and following lengthy discussion, *the Council recommends to the House of Delegates that the AMA:*

- Express strong support for continuation of the PSRO program as a professionally directed effort to ensure that care provided to patients is of high quality, appropriate duration, and in addition is rendered in an appropriate setting at a reasonable cost;
- Express strong support for those efforts currently underway within and outside of government to make the PSRO program more efficient through focused review on problem areas; as versus continuation of the process of reviewing 100% of the federal program admissions;
- Endorse continued availability of federal funds to PSROs for experimentation with new or innovative review methodology; as well as the extension of review of Long-Term Care, Emergency Medical Services, and Ambulatory Care for those PSROs that express the desire and capability of performing such review;
- Endorse further study of ways in which PSRO review findings can be used to effect desired changes in practice patterns in a manner which will ensure continued support of the program by physicians; and
- Recommend continued funding support for research directed toward improving quality assessment techniques, with particular emphasis on developing sample or screening guidelines for adaptation by local PSROs.

### National Professional Standards Review Council

The National Professional Standards Review Council (NPSRC) is mandated by the PSRO law as a physician advisory body to the Department of Health, Education, and Welfare on matters concerning the PSRO program. In July, 1978 responsibility for staffing the NPSRC was transferred from the Public Health Service to the Health Care Financing Administration, despite objections by many that the shift might well lead to greater emphasis on PSRO cost containment objectives, at the expense of the program's medical quality assurance goals. Concurrent with the shift of staffing responsibility for the NPSRC, Helen L. Smits, M.D., Director of the Quality Bureau (the component within DHEW that administers the PSRO program) announced that the Council would serve as a general advisory body to Health Care Finance Administration (HCFA) on issues much broader than PSRO.

At the September 1978 Council meeting, John W. Bussman, M.D., Portland, Oregon was seated as NPSRC Chairman and the addition of Helen B. Barnes, M.D., Jackson, Mississippi, to the Council was announced, leaving only one position vacant on this eleven member group at the time of this report. During this crucial period for the PSRO program, the NPSRC reaffirmed its intent that quality assurance be maintained as the primary PSRO goal.

### Alternate PSROs

In late September 1978, DHEW published final regulations for designation of "alternate PSROs" for areas in which (1) a statutorily preferred, local physician sponsored "priority PSRO" has failed to assume responsibility for PSRO functions, or (2) a poorly performing PSRO is replaced. These regulations provide that if there is more than one qualified proposal for an "alternate" PSRO the following order of priority will apply: (1) other organizations in the area; (2) other PSROs; (3) organizations within the State, but outside the PSRO area; (4) organizations outside the PSRO's State, and (5) "failing all else", carriers or fiscal intermediaries.

The regulations also provide that, in general, a physician sponsored group *cannot* be considered for alternate PSRO status unless it is an existing PSRO for another area; or the medical society in the area has previously taken a position in opposition to the PSRO program.

This particular exception in the regulations is being applied in Louisiana, where three physician groups have been designated as alternate PSROs despite their failure to enroll 25% of area physicians (as required for designation of a "priority" PSRO), because of documented opposition by the Louisiana Medical Society to the PSRO program. It is expected that the alternate PSRO regulations will be applied in Nebraska, where the Nebraska Medical Association remains on record as opposing the PSRO program.

### PSRO Terminations and Nonrenewals

Responding to outside pressure to demonstrate program effectiveness and efficiency, the Health Standards and Quality Bureau has begun to reevaluate PSROs. According to DHEW sources, reevaluations will focus on PSROs which: (1) fail to implement review and other major components of the program in a reasonable and timely fashion; (2) appear to be associated with significant and otherwise unexplainable increases in hospital utilization in their PSRO area; and (3) fail to exercise proper financial management and control procedures. Termination of a PSRO contract, or nonrenewal of a contract at expiration is the most serious course of action available to DHEW when significant problems are identified in PSRO operations or management.

At the time of this reoprt, two PSROs have been notified of DHEW's intent not to renew their contracts upon expiration. Reportedly, several other PSROs have been notified of "problems and deficiencies", which if uncorrected could affect their consideration for contract renewal. While these terminations are significant in that they represent a "tightening up" of the program, they also provide another opportunity for a nonphysician PSRO to be established.

In the case of nonrenewal or termination of a PSRO contract, DHEW will first solicit proposals for another "priority" (physician-sponsored) PSRO. However, if another "priority" PSRO cannot be identified, DHEW will designate an eligible "alternate PSRO."

This House of Delegates, based on its past actions, recognizes the importance of maintaining physician control over quality assurance programs. As these contract terminations or nonrenewals may result in the establishment of nonphysician PSROs, *the Council and its Ad Hoc Committee on PSRO recommend:*

> *that the AMA actively seek to inform all physicians that DHEW may terminate or not renew the contracts of PSROs which are identified as significantly deficient in major areas of PSRO responsibility. Where a PSRO contract is terminated, or not renewed, DHEW may enter into an agreement with an "alternate PSRO", (for the purpose of performing the functions and duties of the PSRO in that area) which may not in all cases be a physician-sponsored organization.*

According to DHEW most decisions to terminate a PSRO contract are based on poor program performance. However, in some cases DHEW has claimed that PSROs lack proper financial and other management controls. In such cases not only the Executive Director of the PSRO, but also the Board of Directors can be found liable for contract obligations. *Accordingly, the Council and its Committee recommend:*

> *that the AMA undertake to inform all physicians as to the general and fiduciary responsibilities incurred by individuals serving on the Boards of Directors of non-profit organizations, and in particular organizations such as PSROs which incur obligations through Federal grants or contracts. The AMA should utilize those channels of communication deemed appropriate to inform physicians of: oversight functions appropriate for Boards of Directors of PSROs; functions appropriate for delegation to staff; the importance of selection and monitoring of PSRO administrative staff; the importance of independent auditing of PSROs; the PSRO Board's legal obligations concerning independent audits; and other topics relevant to prudent, reasonable exercise of the responsibilities and duties of PSRO Boards of Directors.*

### PSRO Data Issues

In addition to the annual debate over program funding, several recent developments affecting PSRO data management threaten continued physician support for the PSRO Program.

(A) In April 1978, Judge Gerhard Gesell of the U.S. District Court in Washington, D.C., ruled that PSROs are not exempt from the Freedom of Information Act (FOIA). This ruling was made in the case of the Public Citizen Health Research Group vs. DHEW and National Capitol Medical Foundation (NCFM is Washington, D.C.'s PSRO). The Final result of this suit could be that previously confidential profiles on the performance of individual doctors and hospitals maintained by PSROs may be subject to public scrutiny.

The Court left open, however, whether specific exemptions under FOIA might be allowed to exempt access to PSRO information, and instructed the defendants to catalogue the PSRO's information and to identify the FOIA exemptions which are considered to apply. The Judge is expected to rule in mid-December 1978, on the applicability of FOIA exemptions to the PSRO's data. Regardless of the decision, Judge Gesell has stated that he will not require disclosure of requested data until all appeal processes are exhausted. Legislation to exempt PSROs from FOIA was drafted by the AMA and other concerned parties, and introduced in both Houses of Congress. The legislation died in the 95th Congress, but is expected to be reintroduced when the 96th Congress convenes.

(B) Under Secretary of DHEW, Hale Champion, is about to implement a policy decision favoring collection of the Uniform Hospital Discharge Data Set (UHDDS) by fiscal intermediaries. A discussion of this issue, and the recommendations of the Council and its Committee strongly opposing the decision to shift responsibility for collection of UHDDS from the PSRO to the fiscal intermediaries is now before this House in CMS Report G "PSRO Data Collection and Management." The Council on Medical Service and its Committee recently considered PSRO participation in multiple-user data systems. As a result of this discussion, also included in Report G are guidelines to assure the integrity, quality, and confidentiality of data managed by a consortia.

### Level of Care—Transmittal 48

A surprise move by outgoing HCFA Administrator, Robert Derzon should speed implementation of revisions in Transmittal 48—"PSRO Determinations of Medical Necessity and Appropriateness of Level of Care." When the Transmittal was first issued in 1977 it required PSROs to consider coverage regulations and rules in making medical necessity determinations for Medicare beneficiaries.

This House, in adopting Substitute Resolution 11, opposed the original version of Transmittal 48 and affirmed that it should be the prerogative of PSROs to make their own determinations as to what constitutes medical necessity for continued hospitalization.

Although Derzon decided to revise Transmittal 48 to allow PSROs to consider the unavailability of an Intermediate Care Facility bed in making determinations for continued hospital stays, the implementation of the revised policy was not expected to take place until new reimbursement practices and other technical details could be worked out.

In his final days as HCFA Administrator, however, Derzon moved to implement the revised policies without waiting for completion of slowly developing changes in Medicare reimbursement rules. At the time of this report, a revised Transmittal 48 was reportedly being refined for issuance.

### PSRO Reimbursement to Physician Consultants

In August, 1978 Chapter XXIV of the *PSRO Program Manual* was revised to allow an increase in the maximum hourly amount paid by PSROs to physician consultants, from $44 to $46.25. The increase was based on the Medicare Physicians Economic Index for the past year. This House of Delegates has supported the position "that physicians should be reimbursed for all mandated PSRO activity and that the level of reimbursement be negotiated by each PSRO with no arbitrary dollar limit imposed on the PSRO by the Federal government."

The Council and its Committee will continue to closely monitor the PSRO program during this period of crucial program evaluation and change. As conveyed in this report, the Council and its Committee remain convinced that strong support should be expressed for continuation of the PSRO program as a professionally directed effort to ensure the quality and appropriateness of care provided to patients.

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# The "Gap-Fill" Method Used in Medicare Fee Profiles

*The following is a report prepared by the Council on Medical Service of the AMA and accepted by the AMA House of Delegates at its November-December Convention in 1978.*

At the 1978 Annual Convention, of the House of Delegates amended Resolution 129 requested the AMA to undertake an indepth investigation of the "gap-fill" method used in Medicare fee profiles, and to initiate appropriate steps and actions, including legal recourse if indicated, to drop the "gap-fill" method from Medicare profiling procedures if the Board of Trustees deems it appropriate.

The Council on Medical Service obtained further clarification on the intent of Resolution 129 from its sponsor, the Texas Medical Association. Concerns in Texas apparently relate to the method used by the Medicare carrier in that state to calculate customary* and prevailing physicians' charges, and to a potential depressing effect this method could have on levels of reimbursement under the program. Under Medicare regulations, a physician must submit at least three actual charges for a given procedure during a calendar year in order for the carrier to establish that physician's "customary charge" for the procedure (which is calculated as the median of the charges submitted). If the physician does not bill for that procedure often enough during the year to enable calculation of a customary charge, the carrier is required to use one of two approaches to "fill the gap" in that physician's customary charge profile:

(a) The carrier must calculate a customary charge conversion factor derived from the physician's known customary charges for other services in the same general category (medicine, surgery, etc.) and apply it to a relative value scale**; or

(b) If the carrier finds that the above method would produce "unreasonable" results, *and if the regional Medicare office agrees,* the carrier may instead establish the physician's customary charge at the 50th percentile or median of customary charges by *other* physicians in the same locality and specialty for this same procedure.

The customary charge established for a billing physician by one of the above two methods is then used for purposes of determining his reimbursement for the procedure, except in years in which he submits enough bills for that procedure to allow normal calculation of his customary charge.

The Medicare carrier for Texas—Texas Blue Shield—apparently utilizes the second of these two methods to "fill gaps" in physicians' customary charge profiles.

The"prevailing charge" for a procedure is defined under Medicare as the *75th percentile* of customary charges for this procedure made by physicians of like training and skill in the area, weighted by frequency. That is, the "prevailing charge" is the amount which would cover the "customary charge" for the procedure in that area at least three-fourths of the times it is performed. The carrier attempts to calculate the prevailing charge for a procedure from the customary charges for that procedure established for physicians in the same specialty and locality.

If customary charges have not been established for enough physicians within that locality and specialty (at least four) to permit the carrier to calculate the prevailing charge, then the carrier is required *by regulation* to use the following alternative approaches to calculating the prevailing charge in the locality from customary charge data, in the order listed:

1) calculating the 75th percentile of customary charges for physicians in the *carrier service area* (in Texas, the entire state) rather than the localities, but still within the specialty;
2) calculating the 75th percentile of customary charges for physicians in the locality *but from all specialties;*
3) calculating the 75th percentile of customary

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*The term "customary" is used in this report solely in its Medicare meaning, wherever it appears.

**Withdrawal of relative value studies by medical societies as a result of federal pressures does not preclude HEW's using such studies.

charges for physicians in the carrier service area and from all specialties;

4) calculating the 75th percentile of an array of all the actual charges made for the procedure (where at least four physicians in the carrier service area have submitted charges for the procedure, but have not performed it frequently enough to permit determination of "qualified customary charges").

The sponsors of Resolution 129 expressed concern that the inclusion of customary charge data for a given procedure from physicians outside the specialty or specialties most involved in using that procedure (approaches (2) and (3) above), would inequitably depress the prevailing charge for that procedure. Because the physicians outside the specialty or specialties concerned used a procedure less frequently, it was reasoned that a higher proportion of these physicians would *not* have established an actual customary charge for the procedure, but rather have been assigned a lower "gap-fill" customary charge set at the 50th percentile, and that these lower "customaries" would act to reduce the prevailing charge to a level that did not truly reflect actual billings.

At its September 1978 meeting, the Council on Medical Service discussed these concerns with a representative of the Health Care Financing Administration; subsequently, the Regional Medicare Director and the carrier for Texas met with the Texas Medical Association to clarify Medicare policies in this regard. It was indicated by the Regional Medicare Director *that Medicare regulations do not allow a carrier to include "gap-filled" customary charges in the array of customary charges from which the prevailing charge is determined: i.e., that only customary charges based on the actual charge history of physicians are used in that array.* Accordingly, the use of customary charge data from physicians outside the specialty or specialties concerned would *not* inequitably depress the prevailing charge level for a procedure.

The Council on Medical Service has examined the appropriate regulations, and concurs with this interpretation. Accordingly, the Council believes, after careful consideration, that action to eliminate the gap-fill method from Medicare profiling procedures would not be appropriate at this time, particularly in view of the lack of any reasonable or equitable alternative method for calculating a physician's Medicare reimbursement for infrequently performed procedures. The Council also agrees with views expressed by the sponsors of Resolution 129, however, regarding the need for continued surveillance of this gap-fill method so as to oppose any future change in its use by carriers which might create such reimbursement inequities. The Council will conduct such surveillance, and suggests that physicians do the same with respect to administration of the Medicare program in their areas.

# The Antitrust Implications of Physician Walkouts

WALTER CHEIFETZ

A U.S. Supreme Court case holding the legal profession subject to the antitrust laws gives both physicians and hospitals something to think about. In a recent case, the Supreme Court ruled that the minimum fee schedules established by the Virginia State Bar Association constitute price fixing by the legal profession and that such authority is illegal under the Sherman Antitrust Act, which prohibits conspiracies in restraint of trade among the states. The lawyers argued that members of the learned professions are not engaged in trade or commerce and should be exempt from the antitrust laws. However, the Supreme Court has thrown that argument out the window.

In its decision, the Court said: "The nature of an occupation, standing alone, does not provide sanctuary from the Sherman Act, . . . Congress intended to strike as broadly as it could in §1 of the Sherman Act, . . . to read into it so wide an exemption as that urged on us would be at odds with that purpose."

This ruling applies just as much to physicians as it does to lawyers. Indeed, physicians did not need this decision to know that they are subject to the antitrust laws. Past decisions foreshadowed the same result. Several years ago the Supreme Court held that a medical association was subject to the antitrust laws where its activities created a restraint of the trade of another group. In that case, the organization was Group Health Association, Inc., a not-for-profit corporation providing medical care on a risk-sharing prepayment basis.

More recently the Justice Department zeroed in on the relative value guides of anesthesiologists. A civil antitrust suit brought by the Justice Department against the American Society of Anesthesiologists is pending in the U.S. District Court in New York City. The complaint charges Sherman Act violations involving anesthesiology fees in excess of $675 million each year.

It was not long ago that thousands of California physicians revolted against malpractice insurance rates and stayed away from their work in protest over the cancellation of a group insurance program. Anesthesiologists, who were among those hardest hit by the proposed rate increases, led the work stoppage rather than agree to premiums in the $22,000 range. The physicians returned to work only after California legislators passed a law providing for a joint underwriting association and agreed to work on other proposals for reforms.

### The agreement is the crux of the matter

From a legal standpoint, there is no important difference between boycotts by physicians and fee-fixing agreements by lawyers. We now come to the most important part of the whole matter: The vice in either case, whether for lawyers or for physicians, is the agreement. If an individual lawyer decides that he will work only for a particular fee, he is not violating the antitrust laws. He gets into trouble when he agrees with other lawyers that neither of them will work for less. So, too, with physicians. If an individual physician decides that, for whatever reason, he wishes to quit practicing medicine or to quit using a particular hospital, that is his business. If, however, he makes an agreement with another physician that neither of them will use the hospital or treat patients, they may be in violation of the Sherman Act because they are acting together in refusing to provide service. The physicians' refusal to practice restricts the availability of medical services, a part of commerce. Further, it indirectly restrains the commerce or trade in which hospitals as well as other physicians engage.

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The cost of such a violation, if it is proved, is very high. Under the antitrust laws, the plaintiff can recover not merely his damages but an amount equal to three times his damages, as well as his attorney's fees.

### Group boycotts generally presumed illegal

In an antitrust suit brought in response to a physician boycott, a plaintiff would have to establish that there was a conspiracy or agreement among the physicians to restrain trade or commerce. The agreement need not be explicit. Nor is it likely that a court would consider relevant a claim by the physicians that they did not intend to harm the patients, hospitals, or hospital employees but intended only to bring down insurance rates. It is well established in antitrust law that if the result of a combination or agreement is to restrain trade unreasonably, the action violates the Sherman Act regardless of the intent of the parties. Further, the courts have held that group boycotts, because of their pernicious effects on competition and their lack of any redeeming virtue, are conclusively presumed to be unreasonable and, therefore, illegal.

Presumably any antitrust suit brought in response to a boycott would be handled in the federal courts, and it would be necessary to prove that commerce had been affected. In the case of a large boycott—one that was statewide, for example—a court would look to the cumulative effect on commerce, which would include the hospital's purchase through interstate channels of drugs, food, supplies, and equipment. It is likely that a court would conclude that a boycott on this scale had more than an incidental effect on interstate trade. Even if it did not, under state laws the physicians would still be liable.

As a result of the California strike in May 1975, hospitals in San Francisco and Southern California lost an estimated $12.4 million. One San Francisco hospital reported an $18,000-per-day loss during the slowdown in surgery and estimated an aggregate wage loss by employees of $500,000.

When the California work stoppage ended, a San Francisco law firm reportedly was in the process of preparing, on behalf of several hospitals, suit papers charging the state society of anesthesiologists and a large number of individual anesthesiologists with alleged violations of the Sherman Act. The suit papers, which were shelved with the truce ending the boycott, included allegations that the defendants in concert had intentionally interfered with the hospital's operation of their lawful business, including interference with the hospitals' relationship with their employees; that the defendants were attempting to coerce the hospitals and the public to pressure the legislature to enact certain legislation; and that the defendants conduct in concertedly refusing to provide services at the hospitals' facilities and in encouraging others to do the same was essentially a group refusal to deal and a per se violation of federal and state antitrust laws.

### Class action suits common in antitrust cases

The hazard of large-scale financial liability must be carefully considered when professionals contemplate group boycotts or work stoppages. Antitrust actions might well be brought on a class action basis, so that all the persons who claimed that they were laid off or denied medical services might sue the participating medical groups and any cooperating hospitals. Antitrust judgments running to many millions of dollars are common, and the hazard must not be overlooked.

The profession must struggle to cure malpractice abuses, and much of what is being done now is exactly right. In the light of the U.S. Supreme Court decision in the Virginia case, however, professionals must recognize that engaging in a group boycott may be a case of jumping from the frying pan into the fire.

# The Role of the Small Rural Maternity Department in a Regional Perinatal Care System

URABAGILU NAGARAJA, M.D.

**ABSTRACT—From earliest concepts in the 1930's regionalization was not intended to replace the local level care provided for routine maternity and neonatal cases. Attempts to regionalize by eliminating the first level of care on a local basis were fought off by the hospital users. As regionalization has developed to eliminate high costs, the Level II care center has been eliminated with movement directly from a Level I, local primary care center, to the regionalized specialized care center at Level III. A basic factor in all planning, including the government's guidelines, has become cost concerns. Elimination of Level II will reduce cost by avoiding duplication of services while maintaining good quality maternity care at Level I.**

Early indications of changes to come in maternal and perinatal health care services date back to the 1930's when first principles of medical regionalization were discussed.

Regionalization is the development, within a geographical area, of a coordinated, cooperative system of delivering health care services.

Regionalization planning for maternal and perinatal care has involved a study based upon population needs in the hospitals' and physicians' areas as well as an assessment of the degree of complexity of care each hospital is capable of providing.

Objectives of the regionalized service are to provide quality care to all pregnant women and newborns, maximal utilization of highly trained perinatal personnel and intensive care facilities and assurance of reasonable cost effectiveness.

Contributing to the interest in regionalization has been the development of specialization of care of both the expectant mother and the new born with centralization of expensive equipment and highly trained specialists in one unit within the region.

As more and more technology is developed in obstetrical and pediatric services for care of mother and baby, the economic factor of high cost for the equipment and personnel has advanced the thinking for regionalization.

In the regionalized plan all physicians and hospitals are linked by a communication network to provide expert telephonic consultation as well as a means for continuing education of physicians, nurses and allied health care personnel.

Transportation networks are developed within the region for fast and safe transfer of complicated maternity cases and critically ill newborns.

The regionalization concept faded into the background until federal legislation enacted in 1965 set up the methods for establishing Regional Medical Programs (RMP's) as a part of Comprehensive Health Planning.

Purpose of these RMP's was "through regional cooperative arrangements" to link peripheral medical care institutions to centers of academic excellence to help carry the full benefits of modern medicine to all victims of heart disease, cancer and stroke. Later, the concern was broadened to include all types of coronary care and finally, to maternity and newborn care.

At this time progress in developing RMP's was slowed down by lack of funding. Some areas started to develop RMP's through cooperation of various segments of health care.

Seeing the implications of regionalization to a rural setting with travel distance a major factor, the Connecticut Medical Society's Governing House of Delegates began pushing for use in all hospitals of empty maternity beds for "clean" gynecological and surgical cases in 1967 and 1968.

In April 1970, the Connecticut State Department of Public Health set up minimum requirements for licensing maternity hospitals. This pattern of recommended consolidation was sweeping across the country under the federally mandated programs that were beginning to develop. In April 1971, the Connecticut House of Delegates again passed a resolution repeating its 1967-68 position for the use of

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maternity beds for "clean" gynecological and surgical cases. A two-part study completed in early 1971 entitled, "Obstetrical Services in Connecticut," developed recommendations for possible ways to reduce the oversupply and maldistribution of obstetrical beds in the state.

Reactions to this study ranged from highly emotional opinions to conservative inter-hospital dialogue which resulted in implementation of some of the recommendations.

The Connecticut State Department of Health adopted new rules to allow general surgeons to admit clean female patients to maternity departments.

In June 1971 the Connecticut Hospital Planning Commission presented a plan under which hospitals could examine the feasibility of merging their obstetrical services with those of another hospital. The hospital study was to find possible ways to reduce the oversupply of beds in certain areas and lack in another to counteract the maldistribution of obstetrical beds throughout the state.

Later, pressure from the Connecticut Commission on Hospitals and Health Care, successor to the Connecticut Hospital Planning Commission, led small institutions with under-used maternity departments to take a second look at the monetary investment in relation to services given and return to the hospital budgets.

Congress gave a boost to regionalization in Public Law 93-641 effective on January 4, 1975.

The basic concept was that each state should be sub-divided into a number of health service regions. Each region was to contain an appropriate number of people to be served together with health personnel, agencies and institutions to provide the necessary services.

Under Public Law 93-641 the various agencies incorporated into the system will eventually replace agencies which have existed under the Hill-Burton Act, Comprehensive Health Planning and Regional Medical Programs.

The National Health Planning and Resources Development Act (Public Law 93-641) will affect the way obstetric and gynecologic care is provided in every community, sooner or later.

One of the priorities named by Congress is the consolidation or coordination of obstetric and pediatric services.

Regionalization of perinatal care, it was found, need not conflict with the spread of family-centered childbirth, supporters of family-centered child birth said.

The two movements appeared on the surface to be contradictory. Dr. Michael J. Daly, chairman of obstetrics and gynecology at Temple University School of Medicine, Philadelphia Pa., said in the fall of 1977, "The availability of good tertiary care is important for insuring the safety of family-centered care." With proper planning, regionalization of services can actually serve to increase family-centered child birth.

Regionalized obstetrical care was supported in a resolution adopted by the American Medical Association House of Delegates 1976 annual convention.

The association's special study committee found "limited experience with regionalization has shown that it can work with benefits to both patient and attending physician."

The resolution gave AMA's approval "in principle" to regionalization of obstretical services in the United States.

State medical agencies, the resolution said, should be urged to provide leadership in applying regionalization to their particular areas.

In accordance with the 1975 Congressional Act, Connecticut has five Health System Agencies (HSA's).

The HSA membership includes at least 51 and no more than 60 per cent consumers with the remainder to be representatives of various health-related fields including insurance and pharmaceutical companies as well as physicians and nurses.

Included in the HSA duties and responsibilities are the evaluation of health resources in an area regularly; development of an annual plan for health; review and approval of federal grant and loan applications; and recommendation of construction projects.

One HSA covers 41 towns running from the state's northwest corner of Litchfield Conty to lower Fairfield County. This covers a sparsely populated region, isolated rural and crowded metropolitan areas with high density of population as well as a range of financial means, from low income to high salaried executives.

Obstetricians in northwestern Connecticut have already had warning of what is ahead at state planning levels.

Proposals to close down a maternity department have been made and fought off by a least one small hospital in Southern Litchfield County.

Community support was thrown behind this Hospital's doctors and administration in a community-wide meeting demanding retention of the maternity department.

Consolidation was being advocated by the State Commission with hospitals a considerable distance away.

Mothers objected to traveling the distance as well as losing contact with their own physician.

More than 300 mothers and fathers who had used the threatened hospital's services and others expecting to use them in the near future defended existence of the department as a part of the community life needed by families unable to travel the greater distance both from a monetary and a time standpoint. Families also expressed a strong desire to have their maternity services at a more personal and closer level in a small department in contrast to a larger center with less close contact between patient, physician and staff.

The patient rebellion demonstrated to the state commission (CHPC) that a vast educational program would be needed to sell regionalization of maternal services.

Southern Litchfield County with its secondary state roads and low density of population as well as isolation from a large urban area with expanded facilities does not lend itself to complete elimination of Level I care. One southern Litchfield County hospital, while close to Danbury and New Haven in a geographical sense, is handicapped in travel time by crowded secondary roads reaching super highways to zoom into a higher level care center.

Southwestern Connecticut hospitals are providing Level I maternity and newborn care through physicians that use Level III care at such centers as Yale-New Haven when specialized medical teams and equipment are needed for "high risk" cases. Consultation is also available from this specialized staff.

Since every maternity and neonatal patient presents a potential for unexpected complications, it is the responsibility of the Level I care center to provide emergency medical services competently. In addition there must be a well defined, efficient regional system of communication and consultation between the Level I unit and the tertiary care center such as Yale-New Haven.

Services in Level I should include:

1. Prenatal care for uncomplicated maternity cases and those with minor complications.

2. An active program for the identification and appropriate consultation for the high risk patient at the earliest possible date in her pregnancy.

3. Physically separated facilities for obstetrics, not precluding use of the obstetrical unit for certain clean surgical cases, or the use of the postpartum unit for clean gynecological cases.

4. Competence to manage uncomplicated labor and delivery of normal, term newborns. Personnel in these units should maintain an awareness of new developments in technology and services offered at other units in the system and avail themselves of these services as indicated.

5. Capabilities of continuous electronic fetal monitoring.

6. An active in-service program of education on neonatal resuscitation to produce competence among all delivery room personnel in the immediate evaluation and resuscitation of the newborn. Appropriate equipment should be provided in the delivery room for resuscitation.

7. Uncomplicated neonatal care of infants of appropriate gestational weight who are products of a normal term pregnancy.

8. A defined routine of transitional stabilization, examination, immediate care and surveillance of all newborns.

9. A nursery able to provide supportive care for infants transferred back from Level III care after their acute problems have been resolved and continued growth and development surveillance and family-centered care are best provided in the Level I unit.

10. Management of unexpected complications that arise so suddenly during labor and delivery and immediately after delivery and are of such severity that transfer is impossible. Services and facilities for emergencies should include:

   a. Cesarean section capability within 30 minutes any hour.
   b. Blood available on call on a 24-hour basis.
   c. Anesthesia service on call on a 24-hour basis.
   d. Radiology service on call on a 24-hour basis.
   e. Clinical laboratory service on call on a 24-hour basis.
   f. Capability to initiate intravenous therapy in a newborn.

11. Uncomplicated postpartum care, including postpartum recovery and observation area for mothers and newborns.

12. Management of unexpected postpartum complications.

A Level I unit should have specialists from Level III units on the staff as consultants.

The Level I unit should have a registered nurse on duty at all times whose primary responsibility is the organization and supervision of nursing services in the labor-delivery area, the newborn nursery and the postpartum units.

A licensed practical nurse or nurse's aide, supervised by the professional nurse, may provide personal support of the mother and attend to her personal comfort and needs.

The physician should examine the mother shortly after admission and at appropriate intervals during labor to assess her condition and the status of the fetus.

An initial evaluation of every newborn should be carried out by a physician responsible for the care of the infant or a professional nurse with training and experience in recognizing abnormalities in the newborn.

The newborn infant should be viewed as a recovering patient during the first 24 hours of neonatal life. A highly skilled professional nurse

# in Brief

## A summary of AMA, medical & health news

**The AMA Board** of Trustees approved major expansion of continuing medical education programming at its meeting at Headquarters Feb. 13–15. The AMA Council on Continuing Physician Education and staff of the Division of Continuing Medical Studies will work with an outside consultant to produce programs for physician instruction. Production will begin with four new videoclinic programs and buildup to about 40 programs by early 1982, at which time production will be maintained at around 18 new programs each year. The Board authorized an expenditure of $500,000 in fiscal 1979, with the intention of spending an additional $2.5 million over the next four years. In 1983, income from the project is expected to exceed expenditures, although recovery of the original outlays is not anticipated until 1987.

**The Council** on Medical Service will review AMA policy on physician reimbursement, giving special attention to the concept of usual and customary or reasonable fees vs. negotiated fee schedules. The council's recommendation for the study was approved by the Board of Trustees due to reports that the Administration's NHI proposal may call for fee schedules, reports that HEW staff is discussing reimbursement alternatives, and the possibility of proposed regulations on the subject in the near future.

**A rule proposing access** to employees' medical records should be substantially revised to protect employees' rights of privacy, the AMA testified at a hearing before the Occupational Safety and Health Administration. The proposed regulation would enable OSHA to inspect and copy records held by employers. "Neither law nor necessity confers on OSHA an unlimited right to intrude on the traditional privacy of the patient-physician relationship without the patient's consent," the AMA said. The AMA witness also pointed out that the proposal would give access to the medical files of many private physicians who practice occupational medicine.

**Findings from** two continuing surveys conducted for the AMA by the Gallup Organization and Market Opinion Research were released at the 7th AMA National Leadership Conference held in Chicago Feb. 15–18. Among the results shown by the surveys are that 47% of AMA members and 59% of nonmembers feel there is a need for national health insurance; that a majority of the nation's physicians, including those who feel strongly about the need for NHI, believe the quality of medical care will worsen if NHI is enacted; and that 43% of the public support NHI even if it means an increase in taxes, which indicates that the issue is withstanding the country's "Proposition 13 mood."

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**Tenuate Dospan®**
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**AVAILABLE ONLY ON PRESCRIPTION**
**Brief Summary**

**INDICATION**: Tenuate and Tenuate Dospan are indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use such as those described below.

**CONTRAINDICATIONS**: Advanced arteriosclerosis, hyperthyroidism, known hypersensitivity, or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states. Patients with a history of drug abuse. During or within 14 days following the administration of monoamine oxidase inhibitors, (hypertensive crises may result).

**WARNINGS**: If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle, the patient should therefore be cautioned accordingly. *Drug Dependence* Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of abuse should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with varying degrees of psychologic dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression, changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. *Use in Pregnancy*: Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential risks. *Use in Children*: Tenuate is not recommended for use in children under 12 years of age.

**PRECAUTIONS**: Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hypertension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of guanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.

**ADVERSE REACTIONS**: *Cardiovascular*: Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. *Central Nervous System*: Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache; rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. *Gastrointestinal*: Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic* Urticaria, rash, ecchymosis, erythema. *Endocrine*: Impotence, changes in libido, gynecomastia, menstrual upset. *Hematopoietic System* Bone marrow depression, agranulocytosis, leukopenia. *Miscellaneous*: A variety of miscellaneous adverse reactions has been reported by physicians These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.

**DOSAGE AND ADMINISTRATION**: Tenuate (diethylpropion hydrochloride): One 25 mg. tablet three times daily, one hour before meals, and in midevening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release One 75 mg tablet daily, swallowed whole, in midmorning Tenuate is not recommended for use in children under 12 years of age.

**OVERDOSAGE**: Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phentolamine (Regitine®) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

Product Information as of April, 1976

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**References**: 1. Citations available on request — Medical Research Department, MERRELL RESEARCH CENTER, MERRELL-NATIONAL LABORATORIES, Cincinnati, Ohio 45215. 2. Hoekenga, M.T., O'Dillon, R.H., and Leyland, H.M A Comprehensive Review of Diethylpropion Hydrochloride International Symposium on Central Mechanisms of Anorectic Drugs, Florence, Italy, Jan 20-21, 1977.

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8-3921 (Y587A)

should be responsible for neonatal care and observation during this time.

The nursing care of postpartum patients should be directed and supervised by a qualified professional nurse. Postpartum care should also include education of the mother in infant care.

The feeder hospitals in rural Connecticut supply this Level I care and are less than an hour's trip from a Level III Care Center.

In addition to pre-arranged care, immediate transfer of newborn infants with problems is possible through the special vehicle available from area Level III care centers.

By this direct contact from a Level I, Primary Care Unit, to Tertiary Level III specialized care, it is clear there is no need for Level II.

Cost factors have crept into all regionalization plans throughout the country. Joseph Califano, Health, Education and Welfare (HEW) Secretary, and his staff are taking a second look at health plans and nationwide costs. Proposals made under the 1975 legislation and amendments (PL 93-641) are being carefully scrutinized for areas to reduce present and potential expenses and rising costs of delivery of health care. The original guidelines were called "too strict and unrealistic" by the American College of Obstetricians and Gynecologists. The College said it was not possible to designate any exact number of deliveries per hospital on a national basis to satisfactorily meet all local needs for obstetric care. These strict guidelines, drafted by HEW in a crash program resulting from pressure by Congress to do something, were revealed to the public in September 1977. These guidelines called for consolidation, ideally within five years, of multiple, small obstetric units with low occupancy rates, except in cases of geographic isolation.

The College said the proposed guidelines "subvert the intent of the original planning law—to bring about more local planning and decision-making in health care." It charged "the guidelines are strict national standards which leave little, if any, room for local flexibility." The ACOG submitted its own alternative guidelines to HEW. These ACOG guidelines were designed to give Ervin E. Nichols, M.D., ACOG director-practice activities. ACOG called for a minimum standard of beds for an entire HSA area, not individual hospitals. It would then be up to local areas to decide how they wanted to assign these hospital beds. For most efficient use of hospital beds. ACOG recommended postpartum beds be used for selected non-infectious gynecologic patients. Already there has been an easing back on the guidelines for obstetric services.

Early this year the federal government revised its proposed national guidelines for obstetric services in an apparent reaction to the general public, the physicians and ACOG's protests about the September 1977 stringent regulations.

Under the original regulations critics foresaw a closing of many rural hospital obstetric units as they could not meet the numerical standards.

The revision sets a minimum number of annual deliveries for hospitals handling complicated deliveries but exempts small hospitals which care primarily for normal births.

The original proposal established a minimum of 2,000 deliveries annually in hospitals in metropolitan areas. Numerical standards were required for annual births in smaller areas as well, within the only exception to this requirement, geographic isolation, as defined by patient travel time.

The revised guidelines require Level II and III care centers to have 1,555 births annually and a 75 per cent occupancy rate.

HEW has set no standards for Level I hospitals. This leaves the planning for these centers at the local level.

This revision also frees the smaller units from national standards for occupancy rates.

The original proposal called for at least a 75 per cent occupancy rate in all obstetric units. The revision sets this requirement for average rate only in obstetric units with more than 1,000 annual births.

Regional planning is emphasized in the revision which states, "Obstetric services should be planned on a regional basis with continuing linkages among all obstetric services and neonatal services."

The September 1977 regulations required use of the national guidelines with no flexibility for the region.

The revised guidelines for regional planning follow the recommendations of ACOG Fellow Sprague H. Gardiner, M.D.

Commenting on the revision, Dr. Gardiner said, "Regional planning must include a cooperative, coordinated network of hospitals, physicians, and other health care providers."

The network, he said must provide consultation and referral, patient transport, public and professional education and evaluation of costs and effectiveness.

ACOG policy states one level of high quality maternal health care should be available to all, regardless of age, financial resources or marital status. Care should include both diagnostic and therapeutic services, and should be readily available in both hospitals and appropriate ambulatory care settings. The policy further states:

1. Freedom of choice should be maintained in the physician-patient relationship and in funding mechanisms, patients should have the freedom to select physicians and physicians the freedom to accept patients.

2. Evaluation of medical and professional judg-

ment must be conducted by peers of the providers of services.

3. Physician-directed health care teams should be utilized in maternal care.

4. All commercial health insurance companies and government programs should provide adequate benefits to cover the costs of maternal care.

5. Adequate funding of programs for education, research and evaluation in maternal health should be provided distinct from the costs of patient care services.

6. Information on human reproduction should be a significant portion of the basic education of all Americans. Academic and clinical instructions in this subject should be required in medical and nursing education.

The policy also covers the need for sensitivity in obstetric care, the appropriate role of government funding and the use of incentive reimbursement for physicians in medical shortage areas.

With this year's easing of the national guidelines by HEW it is now possible to permit low-risk expectant mothers to have their children in a Level I center. This can help reduce health care costs by a considerable amount.

The cost of a 48-hour-stay in the alternative birth center Level I is reported to be $450 while a three-day stay in a Tertiary care unit would be at least $1,300.

This lower cost at Level I will help to prevent the escalating costs that have plagued patients, hospitals and third party payers over the recent years.

In addition the patient will have the benefit of a close-to-home environment where care is more personal and family more accessible.

Responsibility rests with the local Level I provider to maintain a department that is economically feasible through its use both as a maternity department and for "clean" gynecological cases.

With centralization becoming such a big factor in all health care services, maternity and newborn care is one area that lends itself to local care for routine cases at a lesser cost than a large regional center.

With the federal government easing up on its regionalization demands, area and local health care centers, together with physicians, must look at regionalization as an opportunity to hold routine services at a community level while complicated maternity and newborn have the facilities, staff and services of an intensive care center available within a reasonable travel time.

With modern techniques in diagnosing early maternal conditions, need for duplicate facilities from the Primary Level I to the Secondary or Level II care stage has been eliminated.

Level II, at its best development, provides only an expanded Level I care on a larger scale without the full advantage of specialized staffs and equipment.

As a result of early detection of complications in both mother and fetus, the number of high risk births at a Level I care center has been reduced to a minimum.

Retention of maternity departments at the community level provides the care necessary for the average maternity and newborn patient without the expense of time and money to travel to a regional facility.

In addition to eliminating the travel and inconvenience to the patient, maintenance of Level I care at the community level will prevent a division at the specialized intensive care unit between cases needing specialization and routine cases that could be better handled at the community level.

With the tie of immediate transfer to an intensive care unit when necessary and the consultation and referral service with Level III care center, there is no need for a stopping point at a Level II care center between the routine and specialized care centers.

Differences between Level I and Level II care units are few, as both must provide prenatal care for uncomplicated maternity cases and those with minor complications.

Level II adds neonatal services for the uncomplicated patients and for a very few minor complicated obstetrical problems. In addition Level II units provide social services either through a hospital department or public and private agencies such as homemakers services, day care or legal aid among the services.

With careful coordination between Levels I and III, the artificial difference that exists between Levels I and II will be eliminated without loss of service to any maternity patient or newborn.

The uniquely sophisticated equipment in Level III care will be consolidated at one care center to save cost and be available to experienced personnel with training to cope with a large case load saving costs for overall operation of the unit.

Utilizing the special Level III services will eliminate the need for closing Level I care centers that will serve as feeders to the concentrated specialized services.

Definite guidelines, policies and procedures must be drafted to operate the referral system from Level I to Level III with physicians and nurses trained to accept the referral system.

Once guidelines are established they should be followed until the periodic evaluation demonstrates the need for a change.

At first glance, concept may appear contradictory to the family involvement now planned by many families, but upon analysis, regionalized care may become a part of the experience if the expectant mother's condition requires Level III care.

Expectant parent education, a shared child birth experience, parental education in newborn care, relationship of the family's siblings in the prenatal period as well as with the newborn and family planning may be continued in a cooperative plan between Level I and Level III. This should be incorporated in the policies and guidelines established to guide both Level I and Level III institutions.

Regionalization treated from the professional level and the family experience may be brought into the maternity-newborn care services without loss of contact between physician and family at lower cost than maintaining duplicated services if all guidelines and policies are established at the outset of the program.

Regionalization should not mean removal of a service at a local level but should be on the basis of more specialized service for high risk and difficult cases at a regional center.

Physicians must begin to think in terms of improved perinatal care as well as the care of the newborn infant and mother following delivery.

Any move to develop regionalization or to specialize services must have cooperation of physicians from the local level through to the regional unit.

The population must be considered and its requirements for prenatal and perinatal services determined in establishing the region. The region may be defined as a medical service area.

The region must consider the best placement of highly specialized equipment in relation to the geographical area being served as well as the population. Distance necessary to travel to the regional center must be a determining factor in setting levels of maternal service available within the region.

In New England where travel is quicker with super highways and an adequate number of vehicles, one Level III or tertiary care unit for all the serious types of maternal-fetal and neonatal illnesses and abnormalities may serve a large area.

Mountainous regions without a super highway network, isolated pockets of population and sparsely populated regions should not be forced into a regional system.

Western plains and the southern mountainous areas would encounter difficulties in providing adequate speedy transportation necessary as part of the regional plan.

The regional area should have its own feeder hospitals in the outreaches, within reasonable travel time. These smaller community hospitals would provide care for uncomplicated maternity cases and normal newborn infants.

Level III or tertiary care would be provided at the regional center where specialized services for complicated maternity patient and the critically ill newborn would be available.

All of the serious types of maternal-fetal and neonatal illnesses and abnormalities would be handled in this Center. The region should have 8,000 to 12,000 deliveries yearly including those at the Center.

Level III Care Centers would provide these services:

1. Prenatal Care—Outpatient and Inpatient. Full range of prenatal care for normal and complicated patients to be provided.

2. Intrapartum and Postpartum Care designated areas for intensive and postpartum care. Twenty-four hour anesthesia service, 24-hour blood bank, and radiology and clinic laboratory services.

3. Normal and Complicated Neonatal Care.

Facilities for normal, moderately ill and extremely ill infants with the neonatal intensive care unit staffed and equipped for the care of critically ill infants.

Other responsibilities:

1. Consultation—around the clock telephonic service.

2. Transport of patients—equipment and trained team.

3. Preparatory and continuing education—teaching and training medical students—continuing and refresher education.

4. Evaluation of functions and results. Develop mechanisms for reporting results and analyzing these to assess accomplishments or deficiencies of function within the regional system.

5. Research—to develop new knowledge in reproductive biology and in related aspects of behavioral science.

The word "referral" could easily replace regionalization if proper planning is used to implement the program to deliver the best possible care at the lowest possible cost.

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9. Safety Of Home Delivery For Healthy Gravida Supported. Ob GYN News. July 1, 1976. Volume 11, Number 13

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# The Computer in the Medical Office

JOHN R. HAYES, M.D. AND PAUL R. TRUEBIG

**ABSTRACT—In an effort to control the ever-increasing paper flow in the medical office, a mini-computer was installed in a two-doctor practice. Experience has been gained in the use of the computer over a period of 12 months and results are analyzed. Benefits have included improved practice management with reduction in clerical chores. Quality of care was enhanced with accurate diagnostic and morbidity statistics. Drug interaction was more readily assessed and the hazards of polypharmacy reduced. Research in primary care was facilitated with the ability to conduct retrospective analysis of practice data. It is concluded that mini-computers have developed to the point of being useful and cost-effective tools within a small medical office.**

## Introduction

Medical practice in the office setting has become more complex. The amount of paper work generated in the average practice has grown exponentially. With the development of multiple in-office procedures has come increased requirement for third-party reports and detailed record keeping. The cost of clerical support has thus become a dominant factor in office economics.

In an effort to control the ever increasing load of paper work various solutions have been adopted.

Many practices continue to use variations on ledger cards or peg board systems. These manual methods have the advantage of simplicity and low cost. However, they have the disadvantage of requiring hand-written entries and time-consuming work to extract meaningful data. Compared to a sophisticated computer-based system, these manual methods have been described as dinosaur-like.[1]

A second solution has been to use an outside Service Agency with batch processing on a large computer. This has the advantage of transferring some clerical work out of the office and gives neat, well-tabulated reports and statements. Problems arise in that it removes control from the physician's own staff. Raw data still has to be collated into a form suitable for the agency and confidential practice information is released outside the office. There is another and less obvious disadvantage in that outside systems are standardized and cannot make allowance for individual variations in a practice. Finally, it is difficult to utilize a commercial service agency to obtain useful clinical data.

Computer development has reached the stage where it can be integrated quite successfully into the office routine. Utilizing the power and speed of a new generation mini-computer has simplified management problems both administrative and clinical. Staff is relieved of many time-consuming chores, patients get better service, and the physician obtains full and accurate information on his practice.[2 3 4]

It was decided twelve months ago to install a small self-contained computer within our medical office. There are presently two physicians in the group practicing both family and internal medicine. The practice provides care to about 2,000 families or roughly 6,000 patients. Volume is increasing and a third physician is expected to join the group within the next few months.

All programming has been done within the office and results indicate that the use of a small computer is not only feasible but is a most desirable method of dealing with complex paper flow and reporting requirements.

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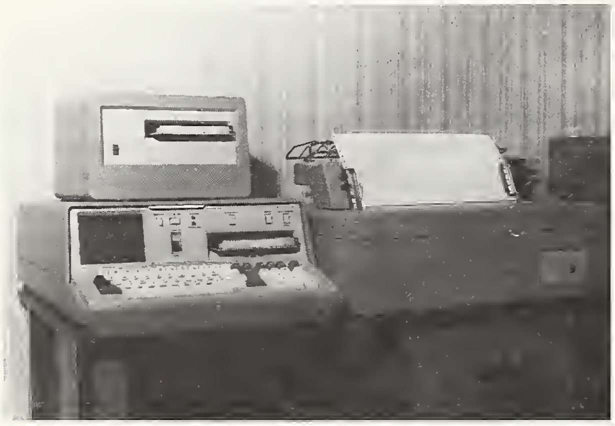
### Hardware

We utilize an IBM 5100 mini-computer with 32K of memory, auxiliary tape drive, and high-speed printer. This configuration allows us to keep full control of procedures performed and can cope with a practice size of 3,000 families or roughly 10,000 patients. Since that time IBM has introduced an upgraded version of the mini-computer known as the 5110. This has the advantage of high speed disc drive with a capacity to handle 9,000 families representing about 28,000 patients. The computer system is modular and a larger number of patients can be accommodated in the future by upgrading the hardware.



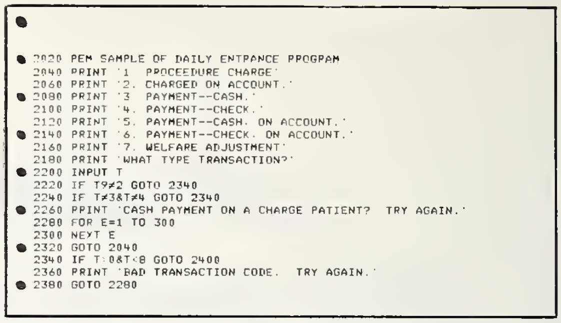
The 5100 includes a powerful central processing unit (CPU) with full-size computer function in a compact portable unit. This includes the usual alpha numeric keyboard with special function keys, convenient small screen display unit and internal memory of 16 to 64K depending on requirements. The CPU is self-contained when used with cassette tapes and may be transported for use either in the office or at home.

The 5103 printer provides clear, legible hard copy printouts suitable for use with insurance forms, patient statements, and clinical reports. (Figure 4)

### Software

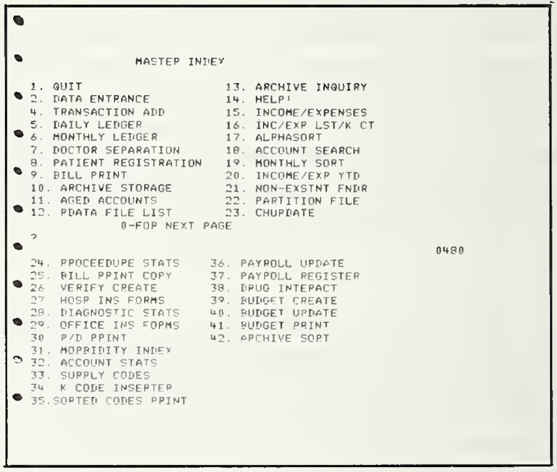
No matter how fast or sophisticated a computer may be the final results are very dependent on the quality of software programming. Information processing in the modern medical practice is complex. Solutions have to be simple and yet flexible enough to work reliably under all conditions. All programs are in BASIC language, an example of which is shown in Figure 1. This indicates how checks are built into the system to obviate operator error. Using a simple programming language allows us to make changes at will without relying on outside professional help.

Programs tend to grow in number as experience is gained and new applications are devised for computer analysis. Our present Master Index contains 42 different programs, all developed as need and experience dictated. (Figure 2)



```
2020 PEM SAMPLE OF DAILY ENTPANCE PPOGPAM
2040 PRINT '1  PPOCEEDURE CHARGE'
2060 PRINT '2. CHARGED ON ACCOUNT.'
2080 PRINT '3  PAYMENT--CASH.'
2100 PRINT '4. PAYMENT--CHECK.'
2120 PRINT '5. PAYMENT--CASH. ON ACCOUNT.'
2140 PRINT '6. PAYMENT--CHECK. ON ACCOUNT.'
2160 PRINT '7. WELFARE ADJUSTMENT'
2180 PRINT 'WHAT TYPE TRANSACTION?'
2200 INPUT T
2220 IF T9≠2 GOTO 2340
2240 IF T≠3&T≠4 GOTO 2340
2260 PPINT 'CASH PAYMENT ON A CHARGE PATIENT?  TRY AGAIN.'
2280 FOR E=1 TO 300
2300 NEXT E
2320 GOTO 2040
2340 IF T>0&T<8 GOTO 2400
2360 PRINT 'BAD TRANSACTION CODE.  TRY AGAIN.'
2380 GOTO 2280
```

Figure 1
This extract from the Daily Entrance Programs shows how operator errors can be detected with the program returning to Line 2040 to accept corrected input. Line 2280 is a time delay to allow the printed error message to remain on the screen for operator action.



```
                MASTEP INDEY

 1. QUIT                    13. ARCHIVE INQUIRY
 2. DATA ENTRANCE           14. HELP!
 4. TRANSACTION ADD         15. INCOME/EXPENSES
 5. DAILY LEDGER            16. INC/EXP LST/K CT
 6. MONTHLY LEDGER          17. ALPHASORT
 7. DOCTOR SEPARATION       18. ACCOUNT SEARCH
 8. PATIENT REGISTRATION    19. MONTHLY SORT
 9. BILL PRINT              20. INCOME/EXP YTD
 10. ARCHIVE STORAGE        21. NON-EXSTNT FNDR
 11. AGED ACCOUNTS          22. PARTITION FILE
 12. PDATA FILE LIST        23. CHUPDATE
             0-FOP NEXT PAGE
 ?
                                                      0480
 24. PPOCEEDUPE STATS     36. PAYROLL UPDATE
 25. BILL PPINT COPY      37. PAYPOLL REGISTER
 26  VERIFY CREATE        38. DPUG INTEPACT
 27  HOSP INS FORMS       39. BUDGET CREATE
 28. DIAGNOSTIC STATS     40. BUDGET UPDATE
 29. OFFICE INS FOPMS     41. BUDGET PRINT
 30  P/D PPINT            42. APCHIVE SOPT
 31. MOPBIDITY INDEY
 32. ACCOUNT STATS
 33. SUPPLY CODES
 34  K CODE INSEPTEP
 35.SOPTED CODES PRINT
```

Figure 2
This is the Software Menu or list of programs developed over a 12-month period. Any program can be accessed by inputting the index number.

All patient contacts within the practice are recorded throughout the day. The system can accept data entered in any order, making full allowance for variation in day to day activity. For simplicity all patient contacts are entered serially as they occur, ranging from hospital consultation and office procedures to patient charges and payments. All information is coded in such a way that entry is simplified and safety checks have been developed to guard against errors that occurred during the early days of operation. All information entered is retained on tape for future analysis. Staff is trained to use the system and produce reliable, consistent results with a few hours of practice.

Once the raw data has been entered into the system, it is sorted internally by the CPU to provide meaningful information for the physician, the office staff, and the patient. Internal sorts take time, averaging about 12 hours. However, the advantage of the computer is that this work can be done in the office overnight without staff in attendance. The sorted information is available to all concerned by the following morning.

### Operation

As presently developed, information processing is handled according to the flow chart depicted in Figure 3.

Each day all physician and patient procedures are entered on tape. This information is used to generate a daily ledger and daily procedure and diagnostic statistics.

Standard AMA third-party insurance forms are printed at the time of data entrance, ready for physician's signature. This eliminates one of the most troublesome aspects of modern office practice. The completed AMA form is attached to the patient's signed insurance form ready for forwarding the same day.

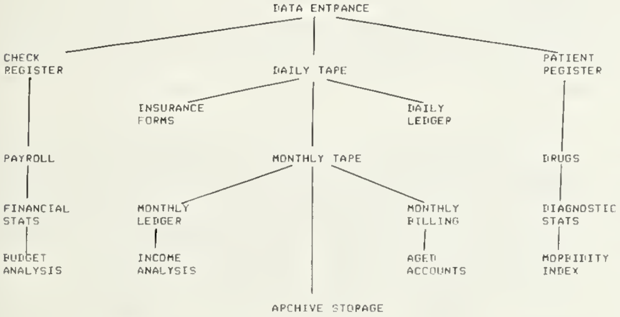


Figure 3
Flow Chart indicating logical progression from initial daily input to final analysed information print-out.

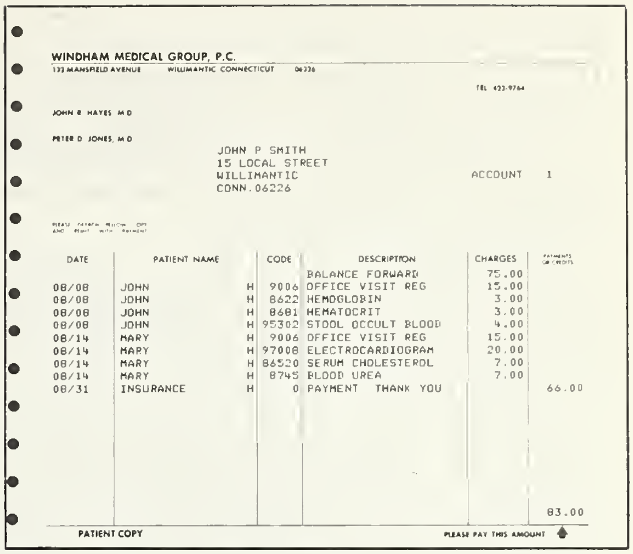
The daily information is then transferred to a monthly file for storage. At the end of the month this file is sorted by the computer to provide practice profiles by physician, by procedure, and by patient. Detailed patient statements are printed automatically at the end of each month. (Figure 4)

Aged accounts are generated for 30, 60, 90 and 120 days. Diagnostic and procedure statistics are available to each doctor. Morbidity indexing with printout of patients by primary diagnosis is also generated. Finally, information on the monthly tape is transferred to an archive tape for long-term storage. All procedures and patient contacts may be retrieved for the previous 12 months from these archive tapes.

### Clinical Applications

A number of programs have been developed to assist in the clinical work of the practice. These include Diagnostic and Procedure statistics together with Morbidity Indexing as noted above.

Indexing was extremely useful when it became necessary to contact diabetic patients taking the drug Phenformin following its withdrawal from the market by the FDA. On request, the computer printed out a list of all patients seen during the year with the diagnosis of diabetes mellitus. A check of the clinical records identified those taking Phenformin and all such patients were contacted within 24 hours.



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PETER D JONES, M D

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15 LOCAL STREET
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CONN. 06226

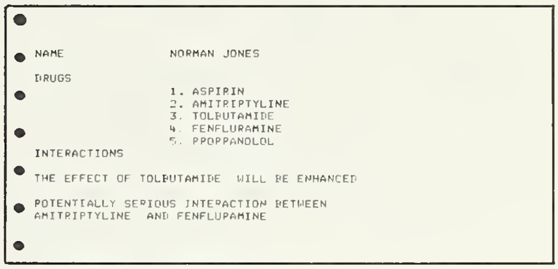
ACCOUNT 1

| DATE | PATIENT NAME | | CODE | DESCRIPTION | CHARGES | PAYMENTS OR CREDITS |
|---|---|---|---|---|---|---|
| | | | | BALANCE FORWARD | 75.00 | |
| 08/08 | JOHN | H | 9006 | OFFICE VISIT REG | 15.00 | |
| 08/08 | JOHN | H | 8622 | HEMOGLOBIN | 3.00 | |
| 08/08 | JOHN | H | 8681 | HEMATOCRIT | 3.00 | |
| 08/08 | JOHN | H | 95302 | STOOL OCCULT BLOOD | 4.00 | |
| 08/14 | MARY | H | 9006 | OFFICE VISIT REG | 15.00 | |
| 08/14 | MARY | H | 97008 | ELECTROCARDIOGRAM | 20.00 | |
| 08/14 | MARY | H | 86520 | SERUM CHOLESTEROL | 7.00 | |
| 08/14 | MARY | H | 8745 | BLOOD UREA | 7.00 | |
| 08/31 | INSURANCE | H | 0 | PAYMENT THANK YOU | | 66.00 |
| | | | | | | 83.00 |

PATIENT COPY
PLEASE PAY THIS AMOUNT

Figure 4
This example of a monthly patient statement shows the detailed breakdown of charges generated automatically from the sorted monthly file.

Another useful clinical application has been in the field of drug incompatibility. One program allows a patient's current medications to be listed together with any proposed additions. If there are any known incompatibilities between the drugs concerned, the computer check will uncover this within seconds of inquiry.[5] (Figure 5)



```
NAME                NORMAN JONES

DRUGS
                    1. ASPIRIN
                    2. AMITRIPTYLINE
                    3. TOLBUTAMIDE
                    4. FENFLURAMINE
                    5. PROPRANOLOL
INTERACTIONS

THE EFFECT OF TOLBUTAMIDE  WILL BE ENHANCED

POTENTIALLY SERIOUS INTERACTION BETWEEN
AMITRIPTYLINE  AND FENFLURAMINE
```

Figure 5
Drug Interaction Program.

### Problems

Once the computer was installed we ran into a number of problems which had to be overcome and involved some midnight "debugging" sessions.

Errors occurred in one of three ways: (a) faulty system analysis; (b) programming errors; (c) operator errors.

System errors are inevitable. The ideal would be to have the analysis complete before a system is introduced. However, real-life situations do not always work out as intended. Computers are finite instruments and do require time to complete assignments. It was found that initial system analysis had to be modified many times over to achieve optimum use and produce maximum useful information within the constraints of the many requirements of the busy medical office. At this time system errors are hopefully behind us and we have a streamlined and efficient processing system which gives most satisfying and cost effective results.

**Programming errors.** These again are inevitable. "Bugs" will always hide even in the most well-written program, especially when it is custom-designed to solve a particular problem. The only way they can be found and corrected is to run the program and watch for errors of execution. Some errors will be picked up by the computer itself and an error message will be displayed. Other errors are most subtle and can result in data referring to one patient being transferred to another patient's record. This problem was eventually overcome by running our old manual system parallel to the new computerized system for the first few months of operation.

**Operator errors.** These are potentially the most serious problem in that the entire validity of computerized information is dependent on the accuracy of data put into the system. The most critical point was to ensure that the correct patient number was used for data input. After a number of mishaps, a system was evolved whereby all patient numbers entered would be verified by the computer prior to acceptance. This has eliminated the vast majority of operator errors.

The second important requirement is that the operator involved be methodical and conscientious. Careless data entry would ruin even the best designed and most efficient system.

**Cost analysis.** The initial investment required was considerable to a small practice. The hardware cost was of the order of $18,000, with IBM financing 75% of this over a four year period. However, we have found that the initial cost has been more than covered by the combination of tax savings due to depreciation, the avoidance of having to hire an additional full-time clerical employee to handle insurance work, and the improved record keeping and cash flow that resulted from having accurate, timely information at hand.

Monthly maintenance payments amount to $119.00. This ensures that our computer runs reliably day and night. Without this full-service backup it would not be possible to rely on the computer as much as we do.

At this time the advantages of the mini-computer have far outweighed the initial problems of cost and the requirement to develop appropriate software programs.

### Future Applications

The use of a compact, powerful, sophisticated mini-computer within the environment of a medical office is still very much in its infancy. In addition to efficient practice management, there are many research applications which can be developed limited only by the imagination and requirements of the individual user. Morbidity statistics and morbidity indexing provide a start. Direct patient interaction with the computer is possible with automated history-taking. Laboratory procedures and results can be interfaced with the computer to provide expanded physician awareness of potential problems. McDonald has shown that protocol prompting in specific disease situations can improve the clinical performance of the physician.[6]

Karas has shown the use of a mini-computer in other clinical situations such as a community hospital emergency room department can enhance quality of medical care. These procedures can be equally well applied to the private physician's office to the eventual benefit of both physician and patient.

In conclusion, on a less serious note, it may be stated that for those occasional days when life is quiet in the office the IBM plays an excellent game of Checkers and an even more exciting game of Star Trek!

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# The President's Page

## The Elderly Complain of High Costs
## Some Thoughts on the Subject

On March the seventh the leaderships of the Connecticut Labor Council and the Connecticut State Medical Society met, at the request of the former. We learned that many of their elderly, retired members are complaining of their inability to find physicians who are willing to accept Medicare fees as their full fees. We also learned that patients are still surprisingly reluctant to inquire in advance about the costs of treatment, out of embarrassment, too much respect for the doctor or fear of upsetting the person to whom they are entrusting their health and bodies. But when, after the fact, the bills prove overly burdensome these patients then complain. We were asked if we could provide a list of physicians willing to take assignment routinely. We answered that we had no such list and that the preparation of such, were it possible, could cause us more problems with the regulators such as the FTC who have accused us of overly influencing the economic aspects of the practice of medicine. After the meeting, Doctors James, Kamens, Canzonetti and I concluded that this problem should be addressed in my next communication to you.

Despite the onslaught of data banks, computers and freedom-of-information laws, the relationship of physician and patient remains one specially protected, still, by our legal system. We all certainly take proper pride in this ancient and privileged trust we along with the clergy are permitted to hold. But as I hope we all remember, over fifty percent of diagnoses are made before history-taking has been completed and before we have laid a finger on the patient. This is almost a quote of my first professor of Physical Diagnosis twenty-five years ago and I have found it a truism in my practice. I would add, however, that for a history to be accurate and complete, the patient must first repose some trust and confidence in the physician to whom he is about to reveal his intimate and often painful secrets and fears.

Certainly physicians may respond, as I did, that patients have a responsibility to inquire and learn the costs of proposed treatment in advance along with the benefits, risks and possible alternatives. As we talked, I realized that this response cannot excuse the physician from his duty to counsel his patient on all these matters nor from being as sure as he can be that his counsel is comprehended. The recent thrusts of regulators in the area of Informed Consent may be merely another symptom that many physicians are not fulfilling these duties.

It is my experience that such counseling grows easier with practice. Once the patient perceives that his doctor is willing and able to talk of such matters as costs, the patient finds it easier to unburden himself of his true feelings and situation. I do believe that the patient-physician relationship is greatly strengthened through such discussions. It then is easy to make proper and fair financial arrangements without humiliation for the patient and to have a much happier and relaxed patient to boot.

While your leadership would never ask you to accept assignment routinely in all cases, we do urge most strongly that you counsel each and every patient on the scientific and economic implications of your diagnosis and treatment and before undertaking the latter. Proper counseling, acceptance of assignment where appropriate, and financial discussions in advance where possible all may be parts of the answer to often voiced criticisms of physicians. We are accused to being too impersonal, too technical and too aloof. We are seen as unwilling to become personally and intimately involved with our patients' problems. If too many of us persist in such attitudes, we will merely encourage our adversaries to further legislate and regulate our relationships with our patients. The harm that will accrue will not only be to the practice of medicine but to the good and welfare of our patients. Medicine should not be practiced as an impersonal confrontation between a technician called physician and the patient, but between two concerned human beings one of whom happens to be a physician.

Jerome K. Freedman, M.D.
*President*

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**INDICATIONS:** *Therapeutically,* (as an adjunct to systemic therapy when indicated), for topical infections, primary or secondary, due to susceptible organisms, as in: infected burns, skin grafts, surgical incisions, otitis externa; primary pyodermas (impetigo, ecthyma, sycosis vulgaris, paronychia); secondarily infected dermatoses (eczema, herpes, and seborrheic dermatitis); traumatic lesions, inflamed or suppurating as a result of bacterial infection. *Prophylactically,* the ointment may be used to prevent bacterial contamination in burns, skin grafts, incisions, and other clean lesions. For abrasions, minor cuts and wounds accidentally incurred, its use may prevent the development of infection and permit wound healing.

**CONTRAINDICATIONS:** This product is contraindicated in those individuals who have shown hypersensitivity to any of its components. Do not use in the eyes or in the external ear canal if the eardrum is perforated.

**WARNING:** Because of the potential hazard of nephrotoxicity and ototoxicity due to neomycin, care should be exercised when using this product in treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible. In burns where more than 20 percent of the body surface is affected, especially if the patient has impaired renal function or is receiving other aminoglycoside antibiotics concurrently, not more than one application a day is recommended.

When using neomycin-containing products to control secondary infection in the chronic dermatoses, it should be borne in mind that the skin is more liable to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for that patient thereafter.

**PRECAUTIONS:** As with other antibacterial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

**ADVERSE REACTIONS:** Neomycin is a not uncommon cutaneous sensitizer. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin. Ototoxicity and nephrotoxicity have been reported (see Warning section).

Complete literature available on request from Professional Services Dept. PML.

# Reflections from the Dean's Office

## Change Ringing and Sour Notes

ROBERT U. MASSEY, M.D.

In the January 12, 1979 issue of *Science* there is an article describing some current problems at Stanford Medical School.[1] Ten days after it appeared there was hardly a medical school faculty member who had not read Richard Knox's account of Stanford's "fiscal ideological crisis." One professor of medicine said that failure of a department head to have read it should be cause for his dismissal!

Medical schools are not alike, but they have similar problems, distributed in varying proportions. As those problems, especially the economic ones, become more troublesome, ideological positions harden. When resources diminish, each interest group toughens its defenses, seeks out its allies, and hopes that administration will be balanced, but always tilting in its direction.

In most schools this is happening now. Research support has continued to decline, and the anti-intellectualism and anti-scientism of the sixties has not run its course. Support for higher education, both public and private, continues to languish, and the entire medical establishment is under fire, even from those quarters once counted as friendly. When we can least afford it, resources are drawn off and wasted in unprofitable struggles with swarms of regulators.

The natural differences, which always have characterized medical school faculties and which have been a source of vitality and intellectual vigor, now decline into occasions for partisanship. The tensions between basic scientist and clinician, between clinical investigator and practitioner, between surgeon and internist, between generalist and specialist, between social scientist and molecular biologist, between scientist and teacher, between hospital administrator and chief of service, and between everyone and the dean, are no longer the motors which drive the enterprise, but rather provide the energy for acrimonious debate and open conflict. Because so many points of view struggling together can only create chaos, uneasy and unnatural alliances form, which are often not acknowledged and may only dimly be perceived. Words and phrases turn into symbols and are used to mark those who belong to the right side or to the other.

If an academic administrator appears by the choice of a word to lean ever so slightly to one side or the other, he could lose the support of half his faculty. For issues to have the power to disrupt a great institution, opposing sides must seem to be about equally matched. An issue supported by 10 percent of the faculty can disturb, but is rarely dangerous unless it draws, even temporarily, another 20 or 30 percent to it.

All medical schools will face most of the Stanford conflicts in the years ahead. The demands of society will impinge with force, support will continue to diminish, clinical work will provide a larger proportion of the operating funds, and competition for patients will become keener. This may heighten the town-gown conflict; it will bring out the regulators, and there will be talk of have and have-not departments. Clinical divisions will develop entrepreneurial habits, and *strict full-time* will be quietly shelved in favor of faculty practice plans, which is only another phrase for *geographic full-time.* Times of transition are always dangerous.

There will be pressures for more internal accountability to detect moves by the administration to shore up the weak by diverting funds from the strong, and cries of "every ship on its own bottom" will rally the high earners. Shifting funds to support basic science and low-earning clinical departments will be resented and resisted unless the dean can elicit loyalty to the integrity of the school, and can achieve consensus around the institutional mission.

There are manifold existential and historical reasons why any of the three or four missions of an academic medical center ought to be primary. Whether there should be more biomedical researchers produced, or more practitioners; more generalists, or more specialists; more research, or more clinical work, are questions for medical sociologists and health policy makers. They are good questions for which there are no good answers.

Meanwhile medical schools will need both to adapt to social pressures and straitened circumstances, and to influence successfully those who make public policy; however, in adapting, there is the danger of loss. Abraham Flexner, writing of the German schools after World War I, noted: "The struggle for existence has intensified competition and lowered its tone. Personal, sectarian, and reactionary mechanisms have, it is said, become more mischievous; . . . the authority . . . of cliques become more powerful."[2]

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

WORKING FOR ALL....

This year is a very special one because it marks the 50th anniversary* of the first prepaid hospital plan in the country — the forerunner of the Blue Cross and Blue Shield concept as it is known today.

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*Here in Connecticut, a plan for hospital care was incorporated in September 1936, with the first group enrolled six months later.*

*In December 1948, Connecticut Medical Service (CMS) was created for the purpose of establishing a non-profit medical/surgical service plan.*

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# The Physician's Duty to Disclose: The New York Cases I

JOSEPH M. HEALEY, J.D.

The field of medical law is permeated with complex concepts and principles difficult to apply in specific contexts of medical practice. Two prominent examples are the physician's duty to communicate information to the patient and the doctrine of "wrongful life." During the usually calm period between this past Christmas and New Year's Day, a pair of cases dealing with these two areas was decided by the Court of Appeals in New York. These cases have attracted widespread notice and deserve special attention.

In the first case,[1] a 57-year-old woman gave birth to a child afflicted with Down's Syndrome. She and her husband filed suit against her gynecologists/obstetricians alleging that they had failed to advise her of the increased incidence of Down's Syndrome in children born to women over 35, and had failed to advise her of the availability of amniocentesis for pre-natal diagnosis. They sought damages on behalf of the infant for her "wrongful life," and on their own behalf for the expenses of institutionalization for the child, for the emotional and physical injuries suffered by the wife, and for the emotional injuries suffered by the husband.

In the second case,[2] a woman whose prior child had been born and had died with polycystic kidney disease, gave birth to a second child afflicted with the disease who also subsequently died. She and her husband filed suit against her obstetricians alleging that they had negligently advised them that polycystic kidney disease was not hereditary and that the chances of conceiving a second child with the disease were "practically nil." The parents sought damages on behalf of the infant for her "wrongful life," on their own behalf for the expenses they incurred in the care and treatment of the child before her death, and for the emotional and physical injuries suffered by the wife and the husband.

In both cases, the parents claimed that the birth of their children with their respective medical problems resulted because of the physicians' failure to accurately and adequately communicate information to them. If accurate and adequate information had been provided to the Becker's, they alleged they would have sought amniocentesis. If the test had been positive for Down's Syndrome, Ms. Becker alleged that she would have obtained an abortion. If accurate and adequate information had been provided to the Park's, they alleged that they would not have conceived their second child. The physician's obligation to disclose information to patients is the critical source of responsibility and liability in these cases.

The Court of Appeals, the highest state court in New York, held in the first case that the only legally cognizable action involved recovery of the sums expended for the long-term institutional care of the child afflicted with Down's Syndrome. In the second case, the Court held that the only legally cognizable action involved recovery of the sums expended for the care and treatment of the child until her death. The cases have been remanded to the original court for trial on the merits.

In short, the Court rejected the notion that there was a viable legal theory upon which to hold the defendant physicians liable for either the "wrongful lives" of the children or the mental anguish suffered by the parents. In the lead opinion, Justice Jasen rejected these claims for three reasons: (1) it did not appear that the infants suffered any legally cognizable injuries; (2) the law is not equipped to make the determination of damages which such injuries (if indeed they were to be regarded as injuries) demand; (3) for policy reasons the Court has in prior decisions refused to permit parents to recover damages for their psychic or emotional harm resulting from the birth and gradual death of their child.

The Court held that the causes of action which do exist in these cases are traditional negligence suits in which the plaintiffs must prove that they suffered injuries which were the direct and proximate result of a breach of a duty owed by the defendants.

It is important to remember that there has not yet been any trial on the merits. What the New York Court of Appeals did was to determine which of the claims made by the parents would, if proven, provide a basis for recovery of damages. The implications for physicians of these decisions and of the allegations made by the parents are enormous. More about these implications will be presented next month.

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JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

# STANLEY B. WELD
## 1890 - 1979

Dedication to and diligence in every task he assumed were two of the many attributes which made Stanley Weld stand out among his fellowmen. A physician for whom the care and welfare of the patient were an overpowering commitment, he automatically expected all others to match his expectations of himself. Nor was he loathe to speak his mind when others did not meet his standards, doing so with a mordant wit which could be devastating to the object of his disapproval. This was a cover for the compassion he felt and the duty he owed to those who sought his help. As the record of his professional and public service shows, he was a man who evoked high esteem and confidence alike in his patients and his colleagues.

Born in Winchester, Massachusetts, in 1890, he graduated from Dartmouth College, in which he maintained an active interest in alumni affairs throughout his life, serving as class secretary since 1962. On graduating from Harvard Medical School, he interned at Hartford Hospital in 1916. He joined the U.S. Army Medical Corps in World War I, after which he continued in the Medical Reserve Corps with the rank of Major.

A Fellow of the American College of Surgeons and the American College of Obstetricians and Gynecologists, his primary affiliation was with Hartford Hospital, where he was President of the Medical and Surgical Staff for three years, but he was associated with other Hartford and Connecticut hospitals in attending and consultant capacities.

Active in the Hartford Medical Society, of which he was a Past-President, he was deeply involved in the County Medical Association, serving as Secretary-Treasurer for several years, and in medical affairs on the State and national levels. Among the positions he occupied were membership on the Council of the Connecticut State Medical Society for many years, Secretary of the Connecticut State Examining Board for ten years, delegate to the American Medical Association, AMA representative on the Council of the American Association for the Advancement of Science, and Chairman of the Advisory Committee of the State Journal Advertising Bureau, a national body which benefited greatly from Dr. Weld's deep sense of independence.

But, among his many achievements, the foremost, and the one of which he was justifiably the most proud, was the founding, in 1936, of *The Journal of the Connecticut State Medical Society* (renamed *Connecticut Medicine* in 1958). The first editor, he single-handedly put this publication on its path to success. He prepared the copy for the printer, traveled throughout Connecticut soliciting acceptable advertising contracts, wrote editorials and encouraged authors to submit articles. As the *Journal* developed, he became successively Editor-in-Chief and Managing Editor, retiring after 22 years of accomplishment. Under his leadership, the *Journal* kept abreast of new developments in medicine during a period which portended significant changes in the field. A reading of "A Journey into the Past," a history of the *Journal* from 1936 to 1958, prepared by Dr. Weld and published in the January, 1976 issue of *Connecticut Medicine*, Vol. 40, No. 1, yields ample evidence of his enterprise, dedication and innovative talents. It was indeed fitting that, when the new Medical Society Building was dedicated, one of the rooms was named to honor him.

But Stanley Weld was a man of many commitments and varied interests. The breadth of the man is manifest in the several areas of ongoing participation. He was a man of deep religious convictions. Ever active in his church, The Immanuel Congregational Church of Hartford, he was, *inter alia*, church moderator, church historian and deacon emeritus. He was a Trustee of the Hartford Seminary, a long-time director of the Y.M.C.A., and a past master of the Hartford Lodge of Masons.

A literator at heart, he was also engaged throughout his active life in other fields. An avid golfer until increasing arthritis limited his participation, he was a keen competitor on the local and State levels. For 14 years, he was Treasurer of a rather unique club on an island in Maine, The Great Chebeague Golf Club, about which he authored an interesting history.

That he was by nature a historian is found in the societies in which he was active, such as the Connecticut Historical Society, the Twentieth Century Club, The American Association for the History of Medicine, the Beaumont Historical Club, and the Horace Wells Club, and in the many articles authored by him, such as "Early Medical Practice in Hartford County" and "Saxifrage to Scalpel."

In his 45 years of involvement in medical affairs, Dr. Weld impressed the stamp of his own unique personality on the organizations which he served, and to a degree far greater than do the vast majority of men.

John Donnelly, M.D.
*Psychiatrist-in-Chief*
*The Institute of Living, Hartford*

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# EDITORIALS

## Transfusion Topics—1979

It is unusual for a single issue of *Connecticut Medicine* to be devoted to one topic, but the importance and the universal applicability of transfusion make it appropriate to deviate from the accepted pattern. While the papers in this series do not, in the traditional sense, present an overview they do address many areas of vital concern to Connecticut's physicians.

Much of the stress is on the newer blood components available in Connecticut. In few areas of the country do physicians have such easy access to single donor platelets, granulocytes or frozen red cells. As Drs. Katz, Morse and Silver discuss, their appropriate use can be of great therapeutic value; their improper use wasteful at best and clearly dangerous at worst. A beguiling mystique is developing around these products. Physicians suggest that they are better than their more easily available and less expensive counterparts. For some patients that is true, but as Katz, Morse and Silver point out these costly components should be used only when clearly indicated. Surely, the same consideration applies to microaggregate blood filters, as is so well developed by Snyder. These, too, add to the cost and complexity of transfusion. Evidence of their value is sadly wanting.

Two authors, Snyder and Miller, remind us that transfusion is not without hazard. Miller quotes the incidence of hepatitis from transfusion at a frightening 10% and cites thirteen papers in support. No physician dare be casual with transfusion when such a high rate of such a serious complication still exists. Silver suggests autologous transfusion as an approach that offers striking advantages in appropriate cases. I believe that we will see more autologous transfusions, particularly in elective surgery where a program of pre-surgery deposit can be beneficial.

None of the papers speak to the many important issues surrounding the administrative arrangements by which blood and blood products are made available. We, in Connecticut, have been spared the agonies of blood shortages, commercial blood banks, blood money and similar problems so common in other areas. On a national level, however, these problems are serious and have led to bitter power struggles suggesting to some that "immuno-politics" is a new medical discipline. Dr. Paul Schmidt's review "National Blood Policy, 1977: A Study in the Politics of Health"[1] is a thoughtful and highly personal account of this important and still seething area. Much of the nation is without a completely satisfactory blood program. We are still plagued with serious national blood shortages, despite the imaginative and useful "Euroblood" program that each year imports about 250,000 units of red cells from Europe. While paid donors have all but disappeared from the whole blood scene there is a lively trade in paid donors for plasmapheresis, amounting to over 2 million liters annually. The three major suppliers of blood, the American Association of Blood Banks, the American National Red Cross, and the Council of Community Blood Centers still struggle for the place of honor at the blood collecting table. And finally, the infant American Blood Commission, born of a mating between public and the private sectors, is still gasping for life. Connecticut, by reason of its excellent blood program, is less involved with the serious game of immuno-politics now being played in Washington. None-the-less we should watch the ways in which the National Blood Policy evolves for these may be harbingers of the developing National Health Policy.

Joseph R. Bove, M.D.,
*Guest Editor*

*From the Department of Laboratory Medicine*
*Yale University School of Medicine*

### REFERENCE

1. Schmidt PI: National Blood Policy, 1977: A Study in the Politics of Health. Prog Hem 5:1977, Elmer B. Brown Ed., Grune & Stratton, Inc., New York, 1977

## The Bridgeport Experience: Physician Leadership in HMO Development

Dr. Robert W. Doering has written a very readable story about the development of Physicians Health Services (PHS), the prepaid health plan of Greater Bridgeport Medical Foundation, Inc. Our group at Boston University is proud to have had a role in the evolution of this program, and its steady progress toward excellence represents a fine example of the creativity and vigor of the medical profession when it gets its act together to serve its patients.

Dr. Doering discusses in his article the degree of risk which physicians assume by participating in PHS and he concludes that each individual physician's financial risk would be minimal (about one percent) at least by the early days of PHS's development. And yet he seems to argue that financial risk will be a significant factor in stimulating the physicians to avoid excessive diagnostic and treatment habits. I doubt that having this small amount of physician's income "at risk" would, taken alone, be enough of a stimulus to induce significant changes in utilization patterns of hospitalization, which is at the heart of successful fee-for-service HMO's. It is heartening to see that PHS is also developing effective peer review controls to review hospital lengths-of-stay. The greater Bridgeport area physicians may question whether the huge influx of federal money spent on developing the closed-panel staff-model plan in Bridgeport was a worthwhile investment of the taxpayer's money. I submit, however, that without this stimulus, there would be no Physicians Health Services, and indeed it is extremely difficult across the country to awaken physicians to their potential for organization into cost-effective, high quality, prepaid health care delivery units.

It may well be that the only alternative to a government run health care system is a competition between different types of health care delivery systems—unstructured fee-for-service, fee-for-service HMOs, and closed-panel plans—competing on the basis of price and attractiveness to the consumer. Because the growth potential for the closed-panel plan is much less than that of the foundation, it would appear that the fee-for-service physicians in the Bridgeport community would have little to fear if they make a success of their own plan. In retrospect, it may have been worth the taxpayer's money to fund the closed-panel plan so that its competitor would be activated to provide high-quality cost-effective health services to the Greater Bridgeport Community!

Richard H. Egdahl, M.D., Ph.D.
*Director of Boston University Medical Center*

# Letters to the Editor

### THE FUNCTION OF THE JOURNAL

*To the Editor:* You hit the jackpot with your December 1978 issue of *Connecticut Medicine.* I have been receiving *Connecticut Medicine* for a great many years, more than I would like to mention, and I have rarely read an issue which was so full of important information. For example, the impact of aging on the population utilization of beds in Connecticut and the significance of P.S.R.O. and H.S.A. Your editorial on the same subject was also excellent, as well as the article on the medical legal significance of the package insert. One of the functions of state journals is to provide us with information like this. I realize the significance of this in particular because I am on the H.S.A. Board here in Florida and have been for the last eight years and I am aware of how the bureaucrats are taking over the practice of medicine.

Your January issue was equally great. The informed consent article and the National Health Care planning fact sheet were excellent and I would like to see more of this type of material in *Connecticut Medicine.*

M.A. Crispin, M.D.
West Palm Beach, Florida

## Antiviral Drug Strikes Again

The antiviral drug amantadine was approved by the Food and Drug Administration in 1966 to prevent a type A flu known as Asian flu. Even with this approval, though, the medical community has been skeptical about whether amantadine can really prevent type A flu and whether it is free from serious side effects. The reason is that antiviral drugs are still largely frontier medicine.

When a type A flu called Russian flu struck the University of Michigan at Ann Arbor in January 1978, Arnold S. Monto and his colleagues at the university took advantage of the outbreak to see whether amantadine could indeed prevent type A flu and do so without serious side effects. Approximately 300 subjects took either amantadine or a placebo twice daily for seven weeks—as long as the Russian flu epidemic lasted in the university community. The researchers report in the March 9 *Journal of the American Medical Association* that 5.9 percent of 136 subjects given amantadine came down with Russian flu compared with 20.1 percent of 139 subjects given a placebo. This was a highly significant difference, showing that amantadine's ability to prevent Russian flu was 70.7 percent. Also, amantadine's side effects were mild and stopped when subjects ceased taking it. Monto and co-workers conclude that amantadine can indeed prevent type A flu and do so without serious side effects.—*Science News,* March 17, 1979.

ANNUAL MEETING
*(Continued from p. 260)*

## SPECIAL NOTICES
## CONTINUING MEDICAL EDUCATION CREDITS

### AMA PHYSICIAN'S RECOGNITION AWARD

**The Yale University School of Medicine has accredited the scientific program of the Society's Annual Meeting for Category One Credit toward the AMA Physician's Recognition Award. Credit is granted in this category on an hour-for-hour basis.**

### AMERICAN ACADEMY OF FAMILY PHYSICIANS

**The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for 5-1/2 hours of prescribed credit for the general lectures and the family practice section meeting, and one hour for elective credit for each lecture attended which is presented by the individual specialty section of the Society.**

**HOTPITAL RESIDENTS, INTERNS AND MEDICAL STUDENTS ARE CORDIALLY INVITED TO ATTEND THIS MEETING.**

### SPECIAL NOTICES

THE CONNECTICUT STATE MEDICAL SOCIETY
acknowledges with thanks educational program grants
received from:

Geigy Pharmaceuticals, Ardsley, New York
Eli Lilly and Company, Indianapolis, Indiana
Park-Davis and Company, Detroit, Michigan
The Purdue Frederick Company, Norwalk, Connecticut
A.H. Robins Company, Inc., Richmond, Virginia
Roche Laboratories, Nutley, New Jersey
Smith Kline and French Laboratories, Philadelphia, Pennsylvania

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**Our exhibits contribute to the value of our Scientific Assembly by presenting goods and services of interest and importance to physicians and their families. Personal visits at the booths will increase your understanding of the materials and programs on display.**

### TECHNICAL EXHIBITS

Aetna Life and Casualty, Hartford, Connecticut
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Boehringer Ingelheim, Ltd., Ridgefield, Connecticut
J.C. Carter and Company, Darien, Connecticut
Encyclopedia Britannica, Chicago, Illinois
Hoechst-Roussel Pharmaceuticals, Inc., Sommerville, New Jersey
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Organon, Inc., West Orange, New Jersey
Pfizer Laboratories, Clifton, New Jersey
Southern New England Telephone Company, New Haven, Connecticut
Upjohn Company, Kalamazoo, Michigan
United States Air Force Recruiting Service
United States Army Medical Department
United States Naval Recruiting Service

# NOTICES

### More "Cancer Update '79" Symposia Scheduled

Following the three initial symposia of this series on Urological Cancer, Lymphoma Myeloma, and Breast Cancer, the Society's Cancer Coordinating Committee announces more of these half-day programs, held from 1 p.m. to 5 p.m. at hospitals in the state.

Lung Cancer will be the subject of the symposium held at the Meriden-Wallingford Hospital on Wednesday, May 23. Windham Memorial Hospital in Willimantic will be the site for the symposium on G.I. Cancer on Wednesday, June 13.

This opportunity for physicians to keep up with the fast-changing field of cancer is co-sponsored by the Connecticut State Medical Society, the American Cancer Society, Connecticut Oncology Association, and the Yale Comprehensive Cancer Center. Prior to the afternoon session for physicians, a morning session is presented for nurses to discuss nursing issues related to the same cancer site.

The registration fee is $10 for physicians per session, and $5 for nurses and others. You may register for one or more sessions by sending your name and address with your check to Cancer Update '79, 850 Howard Avenue, New Haven, CT 06519. Please make checks payable to the Connecticut Oncology Association. For detailed information please call the Yale Center at 436-3779 or the American Cancer Society at 265-7161.

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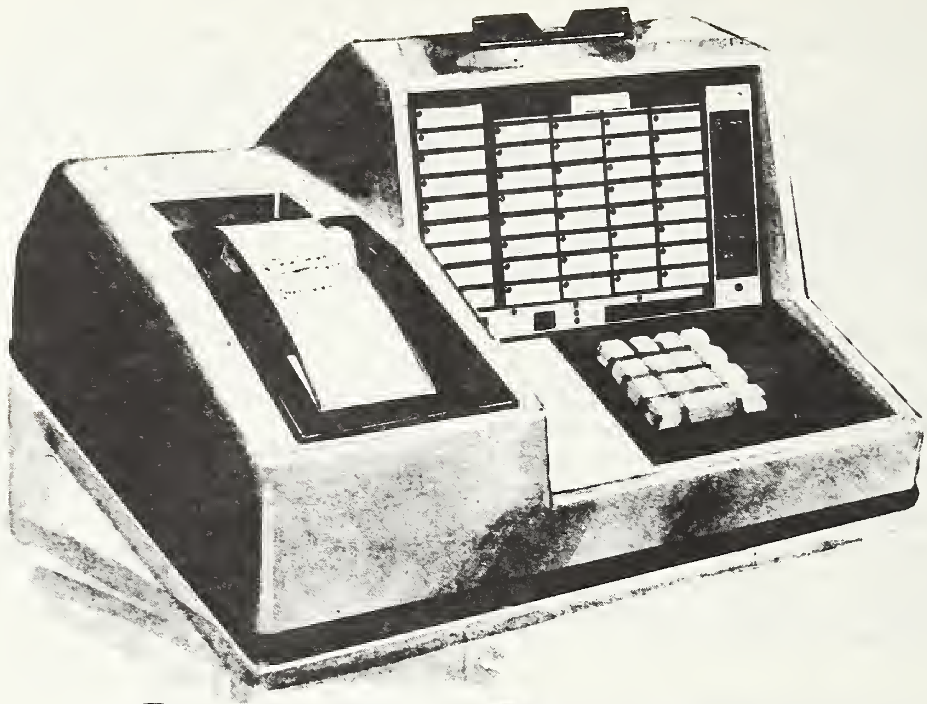
# In Memoriam

**MARTELON, GEORGE F.,** Boston University, 1948. Dr. Martelon was a general practitioner in the Fairfield area since 1950. He was Medical Director for the General Electric Company in Fairfield. During World War II Dr. Martelon served in the U.S. Army from 1943 to 1946. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Martelon died February 6, 1979, at the age of 55.

**RANKIN, BERTRAND F.,** McGill Medical School, 1919. Dr. Rankin was a general practitioner in the Hartford area since 1919 until his retirement. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Rankin died January 6, 1979, at the age of 89.

**ROGERS, WILLIAM J.,** New York University, 1948. Dr. Rogers was an obstetrician and gynecologists in the Fairfield area since 1952, and a member of the Norwalk Hospital medical staff since 1956. He was a U.S. Army veteran, having served with the rank of captain during the Korean War, and was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Rogers died February 18, 1979, at the age of 54.



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*Scientific Activities*

## COUNCIL MEETING

Thursday, February 8, 1979

### Attendance

Present were: Drs. Freedman, James, Backhus, Spitz, Ragland, Jr., Hess, Fabro, Canzonetti, Cramer, Van Syckle, McGarry, Anderson, Magram, Zlotsky, Jameson, Horrax, Shenker, Parrella, Tierney, F. Barrett and Sonnen.

Also present: Mr. Tomat (FCMA), Mrs. Lindquist, Mr. Brunell and Mr. Norbeck.

Absent were: Drs. Kamens, Friedberg, Sadowski, Eslami, Krinsky, Whalen, Beck, Rosenthal, J. Barrett and Bates.

### Approval of Minutes

It was VOTED to approve the minutes of the meeting of January 10, 1979.

### Commission on Hospitals and Health Care

In conjunction with the minutes, it was also VOTED to direct a letter to Governor Grasso mentioning the need for the appointment of a physician to the Connecticut Commission on Hospitals and Health Care and that the CSMS does not retreat from its previous action taken in August whereby Drs. Cramer, Kamens and Rubinow had been nominated for the position.

### Report by AMA Delegation on AMA Convention

Drs. J. Alfred Fabro, Sidney L. Cramer and Jerome K. Freedman reported on activities at the AMA Convention in December, and it was agreed that Dr. Orvan W. Hess would discuss the subject of national health insurance (for 15 minutes) at the next meeting of the Council.

### Reports from Physicians Serving on State and Federal Agencies

HCDC—Orvan W. Hess supplemented a written report by George Bonner on Health Care Data of Connecticut, Inc. (HCDC) and mentioned that efforts to raise funds over the next six months will determine that organization's future. Dr. Bonner was commended by the Council for his in-depth report. PSROs—Andrew J. Canzonetti and Jerome K. Freedman reported on the Hartford County and New Haven PSROs, respectively, and pointed out that both organizations had been audited recently by the government without any problem.

### Report of the President

Dr. Freedman discussed his attendance at American Hospital Association House of Delegates meeting in Washington, D.C. He reported on his visits to the Connecticut Congressional delegation and discussions held on cost containment. It was VOTED that the CSMS consider, on an annual basis, a visit by CSMS leadership to the Connecticut Congressional delegation.

### Committee on Peer Review Systems

After discussion of the question raised by the CSMS Committee on Peer Review Systems relating to physician's fee structure separating the professional components from the materials and overhead component in ambulatory surgery performed in a physician's office, it was VOTED to refer the following motion to the subject committee for evaluation and a follow-up report to the Council.

> "That the Council go on record recommending to the insurance industry that payment be made to the physician for procedures performed in his office which are comparably priced with procedures now only being reimbursed when performed in a hospital."

### Committee on Insurance

It was VOTED firstly to endorse the Commercial Insurance Company Overhead Program; and secondly, to endorse the new Group Life Insurance Policy offered by Group Insurers, Inc. with the contingency that the program must be sold exclusively through the Schiff Agency and not by representatives of the Phoenix Mutual Life Insurance Company or any other agency.

### The Ad Hoc Committee on the CACS Critique

It was VOTED that the newly revised Chapter 9 and the revised Critique be accepted and transmitted to HEW.

### Committee on Drug Abuse Education

Duncan MacMaster, representing the subject committee, reviewed the committee's proposal for a

CSMS Impaired Physician Program. After a brief question and answer period, it was VOTED to approve of the committee report (listed below) and request the committee to proceed with the plan and report back to the Council on its progress.

*"Proposed Plan for a CSMS Impaired Physician Program:*

1. Recruit a voluntary Caring Committee of concerned specialists, by seeking recommendations from key individuals.
2. Provide an inservice workshop program for this group, using talent from within and outside the state.
3. Install a special confidential phone line at the CSMS office, with staff trained to take only what information is necessary for immediate referral to a Caring Committee physician for call back and followup. Work out system for logging calls and referrals.
4. Announcement of program through: A. Traveling presentation to County Association Annual Meetings and CSMS House; B. Article in *"Connecticut Medicine"* Journal; C. Features in CSMS and Auxiliary Newsletters, County Newsletters; D. Direct communication to hospital staff chiefs.
5. Seek periodic reports from Caring Committee for program evaluation."

### Fiscal Items

(a) *Request from AMSA Chapters at Yale and UConn Schools of Medicine:* It was VOTED to approve of the expenditure for two round trip coach fares for students from Yale and UConn to attend the AMSA Convention.

(b) *Request from Committee on Cooperation with the Medical Schools of Connecticut:* It was VOTED to approve of the expenditure of up to $150. in support of the Annual Wine and Cheese Reception to introduce the Society's Preceptorship Program to the first year medical students of the UConn School of Medicine.

(c) *AMA Area Meeting:* It was VOTED to send the President-Elect, Vice-President and a staff member to represent the CSMS at the AMA Area Meeting in Washington, D.C. on April 24 and 25, 1979, at an estimated cost of $900.

(d) *Distribution of Journal to Life Members:* It was proposed that a card be circulated in the Journal requesting Life Members to indicate whether or not they wished to continue to receive the CSMS Journal. The Council confirmed this action.

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on February 8, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

## PHYSICIAN PLACEMENT

*(Continued from p. 262)*

### PSYCHIATRY

Part or full-time position for psychiatrist in specialized substance abuse facility. In-patient and out-patient services. Methadone Maintenance Program. Participation in substantial research program. University appointment. Duties include service as Unit Chief, psychiatric evaluations and supervision of clinical staff. Contact: Administrator, Blue Hills Hospital, 51 Coventry St., Hartford, CT 06112. 203-566-4405.

**Residents in Psychiatry:** First, Second, Third and PGY1 year residency positions available. AMA approved program affiliated with Yale. Intensive clinical experience with outpatients and hospitalized individuals. Seminars and clinical case conferences. Training in special psychiatric problems of children, adolescents, the aged and substance abusers available; individualized track assignments for third year residents. Liberal stipends and full fringe benefits, housing at minimal cost. Connecticut Valley Hospital, Box 351, Middletown, CT 06457.

## PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

### INTERNAL MEDICINE

July '79. Age 27. Nat'l. bds., elig. MD: Wisconsin. Int. and res.: Wisconsin affil. hosp. Also res.: State Univ. of NY-Stony Brook. Grp. or assoc. practice in large or med. community. Stephen Atlas, M.D., 159 Hawthorne Ave., Apt. 262, Central Islip, NY 11722.

**Rheumatology:** July '79. Age 29. Nat'l. bds., elig. MD: Cornell. Int. and res.: Boston City Hosp. Fellowship: Hosp. of Univ. of PA. Wishes grp. practice in large community. Contact CSMS-IM/RHEUM./SPB.

July '79. Age 28. Nat'l. bds., elig-6/79. MD: Georgetown. Int. and res.: Hahnemann. Wishes grp. or assoc. practice in large or med. community. Michael D. Burday, M.D., 139-1 Kirkbride Rd., Voorhees, NY 08043.

July '79. Age 30. Nat'l. bds., elig. MD: University of Miami. Int.: Univ. of Texas. Res.: Univ. of FL. Grp. practice desired in med. community. Charles J. Catalano, M.D., 1810 NW 23rd Blvd., Gainesville, FL 32605.

**GI, Nephrology:** July '79. Age. 32. AB-cert. MD from Syria. Int., res.: Muhlenberg Hosp., NJ. Also res.: VA Hosp., NY. Fellowship: GI-Univ. of Louisville, Neph.-Univ. of Cincinnati. Prefers to practice in med. hosp., where opportunity is to practice gen. IM in addition to specialty. Taha Hamoui, M.D., 9831 Tumerwood Circle, Louisville, KY 40223.

Sept. or Oct. '79. Age 28. Conn. license. Nat'l. bds., elig. MD: Mt. Sinai. Int.: Beth Israel Med. Ctr., NY. Res.: UConn. Wishes grp. or assoc. practice in the lower CT area or Danbury and south of it. Roger H. Karlin, M.D., 52 Currier Pl., Cheshire, CT 06410.

Aug. '79. Age 30. AB-pending. Presently in practice. MD: Israel. Int. and res.: Long Island Jewish Med. Ctr. also int. in Israel. Presently doing ER work. Wishes grp. or assoc. practice in large or med. community. Joshua Lowy, M.D., 4300 Sheridan St., Hollywood, FL 33021.

**Rheumatology:** Aug. '79. Age 28. Nat'l. bds., IM-cert. MD, int., res. and fellowship: Mt. Sinai Hosp., NY. Would prefer Rheu. grp. or multi subspecialty grp. with large Univ. Med. Ctr. affil. Patricia L. Maclay, M.D., 1249 Park Ave., Apt. 13A, NY, NY 10029.

**Cardiology:** Aug. '79. Age 35. AM-cert.-IM, elig.-card. Presently in practice. MD: India. Int. and res.: Worcester City Hosp., Mass. Fellowship: UMass. Would be interested in invasive and non-invasive card. Grp. or solo practice in large or med. community. V. Mahadev, M.D., 429 Case St., Kingsford, MI 49801.

# Revascularization of the Brain Stem

ADAM WESOLOW, M.D., JAMES D. McMAHON, M.D., JOSEPH R. CALI, M.D.,
DELFIN S. SANTOS, M.D., ZBIGNIEW RELIGA, M.D.
AND ANDRZEJ BIEDERMAN, M.D.

**ABSTRACT—The relative incidence of obstructive vertebral arteriopathy, defined as obstructive lesions anywhere along the course of the innominate, proximal subclavian, or cervical vertebral pathway, was found to be much higher than anticipated from the literature. In a continuous series of 201 non-hemorrhagic stroke patients at Mercy Hospital Long Island, only 61 (30%) exhibited pure carotid obstructive disease, 94 (47%) exhibited vertebral diseases only while 46 (23%) exhibited combined vertebral and carotid disease. Other reported surgical series probably represent highly preselected patients, whereas, the vascular surgeon was the primary consultant on the majority of patients in the present series. There were 556 obstructive prevertebral arterial lesions in 140 patients with 228 associated diseases and requiring 232 vertebral and 59 carotid reconstructions. Patient mortality rate using the supraclavicular approach in these poor risk patients was 7.85% within thirty days with 86% good to excellent results in survivors and a post hospital stroke rate of only 2.9% over the average 44.5 month followup period.**

Brain stem insufficiency produced by vertebral arteriopathies differs in diagnostic and therapeutic approach from cerebrovascular insufficiency caused by arteriosclerotic narrowing of the internal carotid artery. Although the vertebral arteries are involved in 60% to 70% of stroke patients, reconstruction of vertebral arteries has not been as widely accepted as carotid arterial reconstruction. In spite of the pioneer work of Cate and Scott,[1] Crawford, DeBakey and Fields,[2] Powers, Drislane and Nevins,[3] Hardin Williamson and Steegman,[4] and Hardin and Poster,[5] there has been slow development of vertebral arterial surgery. There are several reasons thought to be responsible for this state of affairs:

1. Vertebral obstructive lesions can have various causes: arteriosclerosis, tortuosity with kink, external bands, congenital aberrations, tendinous slings and bony compressions (Figure 1). Moreover, these lesions may be found alone or in various combinations thereby increasing the difficulty of establishing a complete and accurate physio-anatomic diagnosis.

2. The hemodynamics of the vertebral arteries result from a complicated surgical geometric unit, consisting of the subclavian and vertebral arteries on the left, and the innominate, common carotid, subclavian and vertebral arteries on the right (Figure 2). In this communication vertebral obstruction will refer to an obstructive lesion at any point(s) along the pathway of this surgical unit.

3. Arteriographic visualization of obstructive vertebral lesions depends upon sophisticated roentgenographic techniques and criteria for inter-

---

ADAM WESOLOW, M.D., Chairman, Department of Surgery, Hospital of St. Raphael, New Haven, CT; Clinical Professor of Surgery, State University of New York. JAMES D. McMAHON, M.D., Director of Surgery, Mercy Hospital, Rockville Centre, New York; Associate Clinical Professor of Surgery, State University of New York. JOSEPH R. CALI, M.D., Director, Surgical Education, Mercy Hospital; Assistant Clinical Professor of Surgery, State University of New York. DELFIN S. SANTOS, M.D., Associate Attending, Mercy Hospital. ZBIGNIEW RELIGA, M.D. and ANDRZEJ BIEDERMAN, M.D., both Copernicus Fellows, Cardiovascular Surgery, Mercy Hospital.

*This work was supported in part by fellowships from the Copernicus Society of America, Philadelphia, Pennsylvania.*

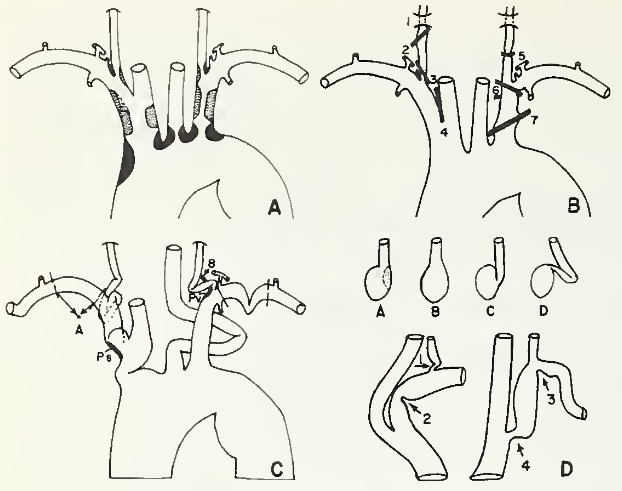

Figure 1
Summary of location of obstructive "vertebral" arteriopathies. A, B, C,: Schemata taken from the RPO, and D, from the RAO arteriographic projection. *A:* Atherosclerotic obstructions. The stippled obstructions, dealt with herein, were all managed via the supraclavicular approach with intact clavicle. Those solid orificial lesions of the arch are excluded from the present study. *B:* Compressive lesions involving bands, slings, aberrant vessels, nerve fibers and osseous compression; *C:* Tortuosity with kink. *D-ABOVE:* Details of oblique views of the vertebral origin from the subclavian artery A—location of frequent atherosclerotic plaques of the subclavian artery producing a hemodynamic obstruction to flow into the vertebral artery B—the configuration after reconstruction, C—the cause of obstruction from the congenitally aberrant posterior (to the subclavian) origin of the vertebral artery, D—patho-obstruction of tortuosity with kink of the vertebral artery; *D-BELOW:* RAO views of the origins of the right subclavian and vertebral arteries: 1-compressive band from sympathetic nerve fiber compression, 2-kink from redundancy of subclavian artery, 3-compression-sling of hypertrophied band of Sibson's Fascia affecting both the subclavian artery and the ostium of the vertebral artery, and 4-atherosclerotic narrowing at origin of right subclavian artery endarterectomized via the supraclavicular approach with intact clavicle. (See Table IV for relative incidence of the various lesions).

pretation for a variety of lesions as well as differential filling and emptying of basilar arteries[6] (Figures 3, 4, 5, and 6).

4. Failure to associate common brain-stem symptoms such as vertigo, headache and blurred vision with vertebral arteriopathy, resulting in failure to comprehend the true clinical frequency of obstructive vertebral arteriopathies.

5. Unwarranted confidence in the collateral ability of the posterior communicating arteries, which in stroke patients, are often small and functionally inadequate. Some groups, therefore, focus attention upon the carotid arteries to the exclusion of the vertebral arteries.

The purpose of this communication is to update[6, 7] one method of diagnostic and therapeutic approach to vertebral arteriopathies and its late results in the hope of providing impetus to further progress in this difficult field of vascular surgery.

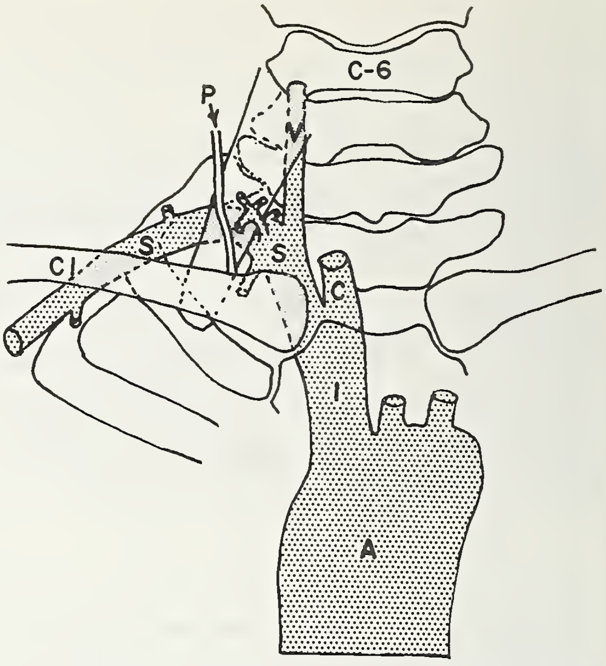

Figure 2
Composite drawing taken from roentgenograms exposed at eight feet from the subject and centered at the supraclavicular fossa demonstrating the important anatomical relationships for the supraclavicular approach. A-aorta, I-innominate artery, C-right common carotid artery, S-right subclavian artery, Cl-clavicle, P-phrenic nerve overlying the outlined scalenus anticus muscle. Note that the innominate bifurcation is normally at the level of the head of the clavicle and the vertebral artery is normally supraclavicular in location.

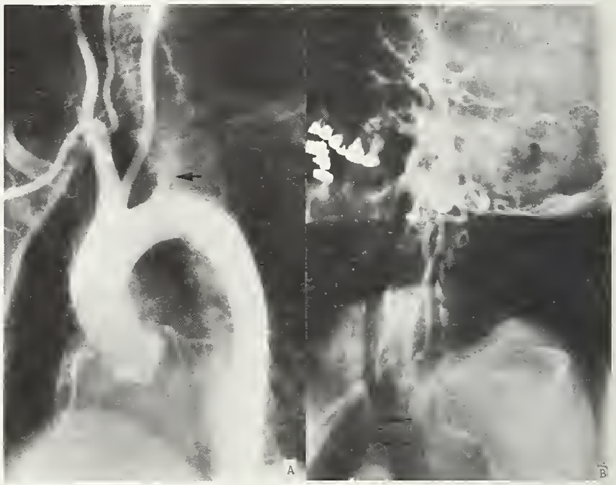

Figure 3
Technique of precerebral arteriography. Using a cutdown to the common femoral artery, a No. 12 French cardiac catheter (occasionally at No. 10 French via the brachial artery) is threaded until the tip is in the mid-ascending aorta. Fifty cc of 80% Angio-CONRAY is injected in one second; serial filming of the patient in the right posterior oblique position *(A)* includes coronary arterial visualization. *B:* Simultaneous filming in the right anterior oblique projection includes aortic root and intracerebral arterial visualization. Films are exposed at four per second for four seconds, followed by two per second for four additional seconds. This case demonstrates proximal left subclavian occlusion (arrow) with reverse flow in the left vertebral artery. "Adapted from Wesolowski et al[6] by permission of the American Heart Association, Inc."

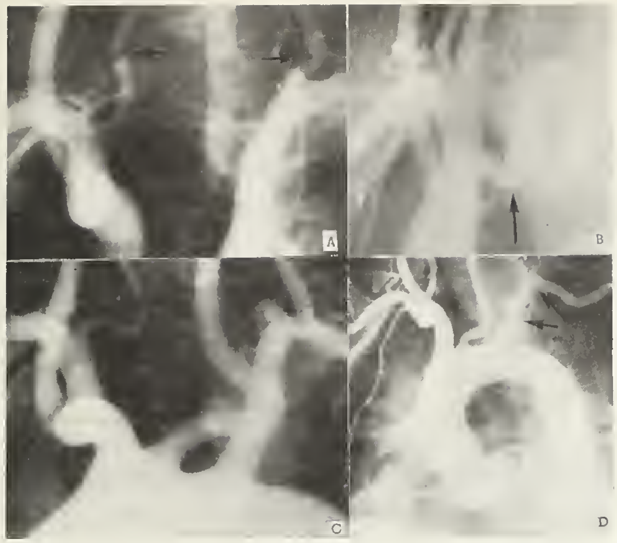

Figure 4
Examples of various arteriographically demonstrated obstructive lesions in the vertebral geometric complex. *A:* Right vertebral band caused by a sympathetic nerve compression (arrow) and left vertebral tortuosity with kink (arrow). *B:* Proximal right subclavian tortuosity with kink (arrow). Note concomitant left vertebral arteriosclerotic narrowing near its origin; *C:* Innominate arterial kink and compression fascial band at origin of right common carotid artery (arrow). Note also kink of right vertebral artery, marked tortuosity of left vertebral artery (kink demonstrated at operation) and tortuosity of left common carotid artery (kink demonstrated at operation); *D:* Proximal left subclavian compressions by fascial band (lower arrow) and fascial sling of Sibson's fascia (upper arrow). Mobilization alone reduced the tortuosity of the left common carotid artery. All lesions were successfully managed surgically via the supraclavicular approach with intact clavicle. "Adapted from Wesolowski et al[6] by permission of the American Heart Association, Inc."

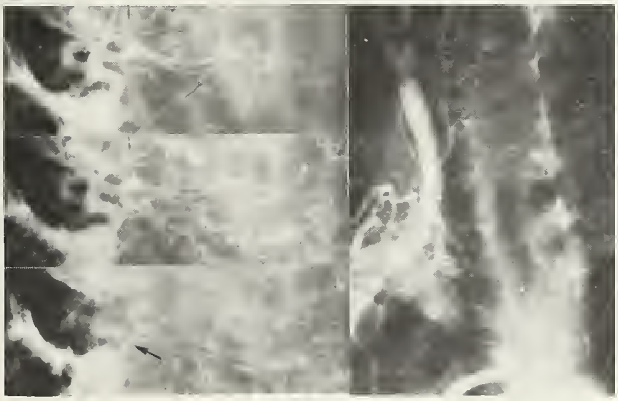

Figure 5
Roentgenographic signs of delayed filling and emptying of arteries supplying the brain. A, B and C are successive exposures showing the area of the circle of Willis and the area of arborization of the basilar artery (v). Note the delay in filling of the basilar distribution in A, equal filling of the carotid and basilar distributions in B, and delayed emptying of the basilar artery (arrow) in C; *D:* Delayed emptying of right subclavian, common carotid, and vertebral arteries distal to an innominate arterial kink stenosis. "Adapted from Wesolowski et al [6] by permission of the American Heart Association, Inc."

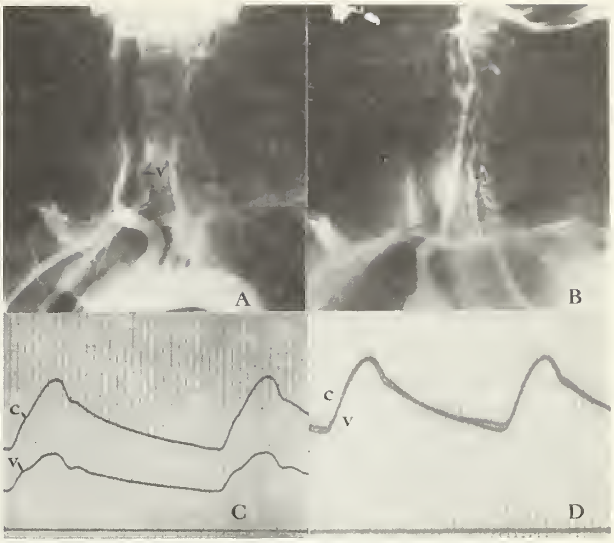

Figure 6
Preoperative precerebral arteriograms and intraoperative blood pressure gradient measurements demonstrating a significant right carotid-vertebral blood pressure gradient in the absence of arteriographically demonstrated obstructive vertebral arteriopathy with resolution of the gradient following operative repair. *A:* Arteriogram in RPO position, and *B* in RAO position showing no definite obstructive lesion along the course of the right vertebral arterial axis (v). The entire arteriographic sequence demonstrated an intracranial internal carotid opacification time of 3 seconds with ½ second delay in filling and 3 second delay in emptying of the basilar artery (basilar/carotid circulation time=2); *C:* Right common carotid (c) and right vertebral (v) arterial pressure studies before, and *D:* after proximal subclavian resection and anastomosis to reduce an obstructive vertebral arterial kink. The patient's symptoms of severe dizziness, imbalance and ataxia are completely resolved one year after operation.

## Patient Population

Surgical management was afforded 201 patients with clinical cerebrovascular insufficiency at Mercy Hospital between 1966 and 1975. Of these 201 patients, 140 demonstrated significant vertebral-basilar insufficiency with or without carotid lesions, while 61 exhibited carotid obstruction only. Of the 140 patients, 94 had only vertebral obstructions while 46 demonstrated obstructive lesions of both the carotid and vertebral systems.

There were 83 female and 57 male patients. The age of patients varied from fifth to ninth decade, with the peak incidence in the seventh decade (Table 1). Patients presented a wide variety of symptoms:

Table 1

AGE-SEX DISTRIBUTION

| *Age* | *Male* | *Female* | *Total* |
|---|---|---|---|
| 40-49 | 10 | 9 | 19 |
| 50-59 | 14 | 23 | 37 |
| 60-69 | 24 | 29 | 53 |
| 70-79 | 8 | 20 | 28 |
| 80-89 | 1 | 2 | 3 |
| Total | 57 | 83 | 140 |

vertigo, dizziness, light-headedness, drop attack, fatigability, episodic weakness, knee-buckling, loss of balance, incoordination, poor handwriting, blurring of vision, diplopia, nuchal, occipital or parietal headache, hearing loss, tremors, twitching, insomnia, somnolescence, paresthesias, numbness, syncope, blackout, transient amaurosis, dysphasia to aphasia, heaviness to stiffness, paresis, paralysis, dysarthria, confusion, disorientation, slow reaction, slow mentation, angina, cynanosis, nausea, cortical blindness, memory loss, dyspnea, agitation, seizures, diaphoresis, bradycardia, personality change, mental deterioration and senility. The incidence of major disabling symptoms is presented in Table II. Patients were referred mainly by internists, otolaryngologists and other vascular surgeons because of severe disability. It should be stressed that in the majority of patients, symptoms were severe; e.g., "vertigo" (dizziness) severe enough to prevent the patient from sitting up to eat, loss of balance causing falling, and headache severe enough to cause patients to contemplate suicide. The majority of the patients were poor-risk because of far advanced cerebral arterial involvement and/or frequent associated disease in other organs.

Table II

PERCENT SYMPTOMATOLOGY AND IMPROVEMENT

| | *Vertebral* | | *Vert. + Carotid* | |
|---|---|---|---|---|
| *Symptoms* | *Pre-Op* | *Post-Op* | *Pre-Op* | *Post-Op* |
| Vertigo | 75.7 | 23.2 | 54.0 | 12.0 |
| Ataxia | 37.4 | 8.0 | 35.0 | 6.0 |
| Blurred Vision | 41.4 | 5.0 | 14.0 | 4.0 |
| Other Basilar | 36.4 | 8.0 | 18.0 | 8.0 |
| Mental Changes | 24.2 | 5.0 | 46.0 | 6.0 |
| Paresis | 19.2 | 7.0 | 46.0 | 14.0 |
| Paresthesia | 25.2 | 8.0 | 40.0 | 16.0 |

Table III presents the incidence of associated diseases. There were 228 associated diseases in 140 patients, mainly added manifestations of arteriosclerosis obliterans or diabetes mellitus.

Table III

ASSOCIATED DISEASES IN 140 PATIENTS

| | *Number* | *Percent* |
|---|---|---|
| Abnormal EKG | 76 | 54.2% |
| Symptomatic A/S Heart Disease | 48 | 34.2% |
| Peptic Ulcer | 3 | 2.1% |
| Diabetes Mellitus | 22 | 15.7% |
| A/S Lower Extremities | 10 | 7.1% |
| Hypertension | 43 | 30.7% |
| Other: Hyperlipidemia, Diverticulosis, Deafness, Carcinoma, Varicose Veins, Chronic Obstructive Pulmonary Disease, Duodenal Ulcer, Aneurysm, Abdominal Aorta, Paget Disease | 26 | 18.5% |

The frequency of obstructive cerebrovascular lesions as identified at operation and/or arteriography is summarized in Table IV. A total of 556 obstructive lesions were found in 140 patients. The majority of subclavian and vertebral lesions were identified as kinks (64 and 159 respectively) or arteriosclerotic plaques (46 and 104) while the majority of common and internal carotid lesions were of arteriosclerotic origin (18 and 68). Kinks apparently result from aging of arteries involving a loss of elastic tissue resulting in arterial elongation. Arterial elongation or redundancy between any two points of arterial fixation can lead to kink obstruction. In occasional patients specific obstructive lesions could not be visualized on X-ray but the radiographic sign of delayed filling and emptying of the basilar artery (½ to 4 seconds) is considered pathognomonic of obstructive vertebral arteriopathy (Figure 5); this conclusion has been verified at operation in such patients with no arteriographically demonstrable lesions (Figure 6). It is of interest that 31% of patients were found on arteriography to have a brachiocephalic configuration of the arch vessels, whereas, it has been reported by Malan[8] that this configuration occurs in only 9% of the population at large.

Table IV

PATHOANATOMICAL LESIONS

| *Artery* | *A/S* | *Compression* | *Kink* | *Total* |
|---|---|---|---|---|
| Innominate | 14 | 5 | 15 | 34 |
| Subclavian | 46 | 37 | 64 | 147 |
| Vertebral | 104 | 23 | 159 | 286 |
| Com. Carotid | 18 | — | 10 | 28 |
| Internal Carotid | 68 | — | 3 | 71 |
| Total | 250 | 65 | 241 | 556 |

### Surgical Approach

The operative approach to all lesions, except those involving the ostia of the great vessels, was supraclavicular with intact clavicle. Since the majority of patients were elderly and poor-risk, this approach was considered safer than thoracotomy. Surgical dissection included a routine approach to the subclavian artery with reflection of the scalene fat pad, excision of the scalenus anticus muscle and avoidance of phrenic nerve injury. In all patients, mobilization of the vertebral geometric unit from the level of the thoracic aorta to the second portion of the axillary artery was performed with division of the internal mammary artery, the thyrocervical axis, and from one to five deep cervical branches of the subclavian artery. Mobilization of the vertebral artery was carried out from its origin to the point of entry into the bony canal of the sixth cervical vertebra. On the right side special care must be taken to avoid injury to the recurrent laryngeal nerve in mobilizing the subclavian and/or innominate arteries.

The type of vascular reconstructive procedure varied with the pathology (Table V). In obstructive lesions caused by compressions, bands or slings, arteriolysis was usually sufficient to correct the obstruction in 25.4% of cases; in some cases arteriopexy was added especially to correct angulation caused by posterior origin of the vertebral artery. In 24.5% of patients, endarterectomy was additionally necessary to remove obstructive arteriosclerotic lesions, while in 38.4% of patients, subclavian resection with or without endarterectomy was carried out to restore an acceptable configuration of the surgical geometric unit (Figure 7). In recent cases proximal subclavian resection was employed and is now preferred for correction of vertebral redundancy with kink, while in earlier cases, distal subclavian resection was used more frequently. Ten percent of patients required vertebral resection: in 3 patients vertebral reimplantation was done; one patient had vertebral-carotid anastomosis. Patients in the vertebral-carotid group had also 59 carotid endarterectomies performed.

## Results

Early and late results of cerebral vascular reconstruction in 140 patients are summarized in Tables II and VI. Patients consist of two groups: those with pure vertebral involvement and those with vertebral and carotid obstructions. There were 11 deaths within 30 days of the last operation producing a crude operative mortality rate of 3.78% and a crude patient mortality rate of 7.85%. The early mortality rate was significantly higher in the vertebral-carotid group, (4.03%, operative and 10.85%, patient) than in patients with pure vertebral disease. Deaths occurred in patients with very extensive cerebrovascular involvement, or in patients with advanced arteriosclerotic heart disease and were caused by fatal stroke in four patients, cardiac deaths in four patients, pulmonary complications in two, and generalized arterial thrombosis in one. Seven patients were lost to followup.

Of all non-fatal complications, ipsilateral hydrothorax, transient (rarely permanent) partial Horner's syndrome, and a variable degree of brachial plexus pain were most common and self-limited. There were also 27 other non-fatal complications: phrenic nerve paresis in four patients, two cases of treatable heart failure, five cases of urinary tract infection, three cases of pneumonia, three cases of postoperative bleeding, and one case each of: recurrent laryngeal nerve paralysis, subclavian artery thrombosis, pneumothorax, supraventricular tachycardia, acute brain syndrome, anaphylactic reaction to heparin, wound seroma, and wound infection.

During the ten years of the present study (average of 44.5 months' observation period) 13 additional patients died: two of stroke, five of cardiac causes, three of cancer, one of diabetic coma and one of gastrointestinal bleeding. The late mortality rate was higher in the vertebral-carotid group, 13%, as compared to 7.44% in the pure vertebral group,

Table V

FREQUENCY OF SURGICAL PROCEDURES

| | *Vertebral* | | *Vert. + Carotid** | | *Total* | |
|---|---|---|---|---|---|---|
| Arteriolysis + Arteriopexy | 49 | 29.3% | 10 | 15.4% | 59 | 25.4% |
| Endarterectomy | 27 | 16.2% | 30 | 46.1% | 57 | 24.5% |
| Subclavian Resection | 76 | 45.5% | 13 | 20.0% | 89 | 38.4% |
| With Endarterectomy | 24 | | 7 | | 31 | |
| Without Endarterectomy | 52 | | 6 | | 58 | |
| Vertebral Resection | 14 | 8.4% | 9 | 13.8% | 23 | 9.9% |
| With Anastomosis | 13 | | 9 | | 22 | |
| With Graft | 1 | | | | 1 | |
| Vertebral-Carotid Anastomosis | 1 | 0.6% | | | 1 | 0.4% |
| Vertebral Re-Implantation | | | 3 | 4.6% | 3 | 1.3% |
| Total | 167 | 100% | 65 | 100% | 232* | 100% |

*Does not include 59 Carotid Operations.

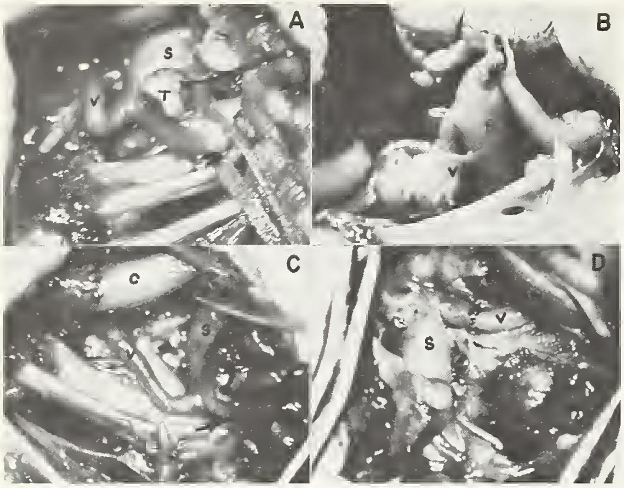

Figure 7

Photographs of operative arterial resections for management of redundancy with kink. V=vertebral artery; S=subclavian artery. A, B and C are operative photographs of stages of distal right subclavian resection in the same patient. *A* shows the vertebral arterial kink after ligature-division of the thyrocervical axis (T). There is an umbilical tape around the distal (to the vertebral artery) subclavian artery. *B:* Elevation of the distal subclavian artery to show subclavian redundancy after mobilization and fascial fixation of redundant loops of the vertebral artery. *C:* Vertebral arteriolysis and resection and anastomosis of the distal redundant subclavian artery. The subclavian anastomosis has retracted deep to the clavicle (arrow), and the vertebral arterial origin has been displaced laterally with reduction of its kinks. Resection and anastomosis of the right common carotid artery (c) to correct redundancy and kink has also been done. *D:* Operative photograph following resection and anastomosis of the left vertebral artery in another patient for correction of redundancy and kink. Vertebral resection is reserved for those few patients in whom the origin of the kinked vertebral artery is so proximal that distal subclavian resection cannot displace the origin of the vertebral artery a sufficient distance to correct the vertebral kink. (These patients are presently managed by proximal subclavian resection and anastomosis). "Adapted from Wesolowski et al[6] by permission of the American Heart Association, Inc."

reflecting mainly the difference in severity of generalized arteriosclerotic involvement. The crude postoperative stroke rate over the entire period of observation was 5.7%; if one excludes the four in hospital postoperative strokes, the post hospitalization stroke rate becomes 2.9%.

One hundred and nine patients were followed for an average period of 44.5 months; 86.2% of patients are asymptomatic or have only mild and non-disabling symptoms (Table II). It would appear that apart from stroke prevention, operation has been helpful in relieving subjective symptoms. 13.1% of survivors in the pure vertebral group, and 15.1% of survivors in the vertebral-carotid group have severe residual or recurrent symptoms; these are traceable mainly to progressive arteriosclerosis or inoperable intracranial involvement.

It is difficult to express in writing the striking improvement in certain patients, who had been previously diagnosed as chronic brain syndrome and postoperatively became "bright-eyed and bushy tailed."

## Discussion

The operative and late results of surgical management in 140 patients with vertebral arteriopathy have been presented. It is important to point out that each patient averaged four obstructive lesions in the arterial supply to the brain, while two-thirds of all patients exhibited significant associated disease. Satisfactory results were observed in 86.2% of long-term survivors. It is most probable that the total surgical management has resulted in stroke prevention; the crude post-operative stroke rate of 5.7% (2.9% post hospital stroke rate) for the entire period of observation (average of 44 months) is undoubtedly a much lower incidence than otherwise would be

Table VI

CRUDE RESULTS

| | *Vertebral* | | *Vert. + Carotid* | | *Total* | |
|---|---|---|---|---|---|---|
| Patients | 94 | | 46 | | 140 | |
| Operations | 167 | | 124 | | 291 | |
| Pt. Rate | | 6.38% | | 10.85% | | 7.85% |
| 30-Day Post-Op Deaths | 6 | | 5 | | 11 | |
| Oper. Rate | | 3.59% | | 4.03% | | 3.78% |
| Pt. Rate | | 7.44% | | 13.04% | | 9.28% |
| Late Deaths | 7 | | 6 | | 13 | |
| Oper. Rate | | 4.19% | | 4.83% | | 4.46% |
| Survivors Followed | 76 | | 33 | | 109 | |
| Asymptomatic | 45 | 59.3% | 15 | 45.5% | 60 | 55% |
| Mild Symptoms | 21 | 27.6% | 13 | 39.4% | 34 | 31.2% |
| Severe Symptoms | 10 | 13.1% | 5 | 15.1% | 15 | 13.8% |
| Crude: Post-Op Stroke | | | | | | 5.7% |
| Lost to Follow Up | 5 | | 2 | | 7 | |

expected in this poor-risk, elderly and stroke-prone patient population without operation. This conclusion is also supported by the observation that during the period of 1964 to 1976, admissions of patients with cerebrovascular diseases to Mercy Hospital increased nearly four times, while hospital mortality decreased to nearly one-half (Figure 8); during this same period the average hospital stay of cerebrovascular patients decreased from 26 days to 13 days suggesting more rapid improvement of increasing numbers of patients.

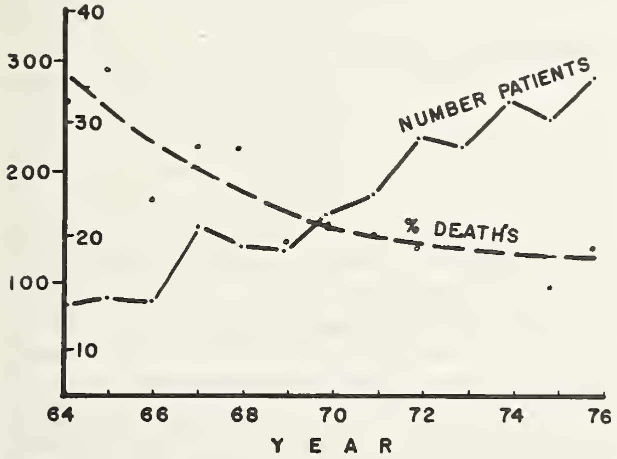

Figure 8
Summary of crude number of cerebrovascular patients admitted (broken line) and percentage of case fatality of cerebrovascular patients (dashed line) at Mercy Hospital by years during the period 1964 to 1976.

The present patient population has exhibited a strikingly different distribution of obstructive extracranial vascular lesions than reported by other workers. Whereas Wylie and Ehrenfeld[9] reported that 89% of their surgical procedures for revascularization was upon the carotid bifurcation, the present communication emphasizes that only 39% of our brain revascularization procedures were upon the carotid bifurcation (Table VII). Our findings correspond more closely to the pathoanatomical studies of Hutchinson and Yates[10 11] who noted vertebral arterial involvement in 60% to 70% of fatal stroke cases. It should be stressed that arteriography performed in elderly patients for reasons other than stroke symptoms (e.g. trauma) may demonstrate vertebral arterial tortuosity or even kinks without stroke symptoms. These patients, of course, are not candidates for revascularization of the brain which is applied only to patients who also exhibit significant clinical cerebrovascular insufficiency.

Table VII

INCIDENCE BRAIN STEM INVOLVEMENT

| *Operation* | *Wylie* | *Wesolow* |
|---|---|---|
| Carotid Bifurcation | 738 (89%) | 148 (39%) |
| Other | 93 (11%) | 232* (61%) |
| Total | 831 | 380* |

*Does not include orificial lesions of the arch vessels which would magnify the divergence with Wylie.

Because of advanced disease and multiple lesions the majority of patients in the present series required two or more operations to achieve optimal results. In dealing with vertebral tortuosity and kink, proximal (or distal) subclavian resection with anastomosis is preferred over the apparent anatomically better vertebral resection and anastomosis. Subclavian resection corrects the lesion at lower risk of postoperative thrombosis because of the larger caliber of artery when compared to the vertebral artery.

Finally, during the course of this study we have become convinced, like Hardin,[5] that the best results with cerebral arterial reconstruction are obtained when all demonstrable obstructive lesions are reconstructed.

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# The Role of Total Parenteral Nutrition and Delayed Hypersensitivity Response in Crohn's Disease

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AND KIRK K. KAZARIAN, M.D.

A young debilitated patient with severe Crohn's Disease with multiple internal and external fistulae received total parenteral nutrition (TPN) and serial delayed hypersensitivity testing as an indicator of adequacy of treatment prior to operative intervention. The details are presented in the following case report.

## Case Report

A 35-year-old white male with a nine-month history of Crohn's ilecolitis associated with a weight loss of 120 pounds presented with multiple perianal fistulae and a peripenile abscess to Stamford Hospital and was admitted for incision and drainage of the abscess and evaluation for definitive treatment of his underlying disease. He had received a short course of steroid therapy and Azulfidine six months prior to admission.

Examination on admission revealed a febrile, emaciated young male in severe distress with perineal pain. He was anemic and had an elevated white blood cell count with a shift to the left. Examination under anesthesia revealed multiple ischiorectal abscesses which required incision and drainage. Sigmoidoscopy showed complete destruction of the sphincter and multiple fistulous tracts. The mucosa beyond the distal rectum was normal. Postoperatively he received parenteral antibiotics, and total parenteral nutrition was started at 45 KCal/Kgr/24 hours with a N/KCal ratio of 1/180:

Diagnostic studies demonstrated a normal upper GI series. The small bowel series and barium enema revealed granulomatous ileocolitis up to the mid transverse colon, and multiple fistulae from the perineum to the retrorectal space and from the termal ileum to the rectum.

The patient was maintained on total parenteral nutrition with complete bowel rest for two weeks and he gained eight pounds. Copious amounts of purulent material continued to drain from the perineum and ischiorectal areas. Intradermal skin testing[7] using 5 recall antigens, (PPD, Mumps, Candida, Trichophytin and Streptokinase-Streptodornase) revealed no positive responses confirming his anergic state.

## Hospital Course

Surgical intervention to control the primary process was postponed because of total anergy and TPN was continued with an increased delivery of 4000 KCal/day and 1/200 N/KCal ratio. He gained a total of twenty pounds on this therapy, and repeat skin testing revealed positive response to all five antigens. Exploratory laparotomy was then performed and moderate inflammatory changes in the distal ileum and right colon were noted. There was no evidence of fistulae to the abdominal wall or pelvis and the retrorectal space was intact. The diseased terminal ileum and right colon were removed and a terminal ileostomy and distal transverse colon mucous fistula constructed.

The patient tolerated the procedure well and had an essentially uncomplicated postoperative course except for mild upper GI bleeding due to erosive gastritis which subsided spontaneously. He was discharged on the eleventh postoperative day. Pathological examination of the specimen revealed widespread changes of granulomatous ileocolitis in a resolving phase, with microscopic demonstration of a fistula into the ileal wall, as well as multiple entero-enteral sinus tracts with granulomatous changes.

## Comments

This case illustrates two important concepts: (A) total parenteral nutrition and complete bowel rest in the treatment of inflammatory diseases of the bowel, and (B) serial delayed hypersensitivity testing as an indicator of adequacy of nutritional support.

Many authors have referred to the use of total parenteral nutrition and complete bowel rest in the management of inflammatory diseases of the bowel[1, 3, 4, 5] and several studies have addressed the

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issue of non-operative closure of enteral fistulae with total parenteral nutrition.[2] [6] In this particular case the preoperative demonstration of fistulae followed by TPN and bowel rest resulted in closure of the fistulae and made definitive resection much simpler and was well tolerated by the patient. However, the most important aspect in the care of this patient was the demonstration of his anergic state after being on TPN for more than two weeks despite a weight gain of ten pounds and normal laboratory values of total protein and serum albumin. The only indicator of persistent problems was the continuing perineal drainage.

Meakins and co-workers[7] [8] have recently demonstrated the adequacy of delayed hypersensitivity skin tests to identify the patient at increased risk for sepsis and mortality. They found in 218 patients so tested preoperatively, 12% (26 patients) had reduced cutaneous responses and a significantly higher rate of sepsis (19%) and mortality (3.1%) rates. Serial skin testing was performed in 178 patients undergoing operation, and in 135 patients who had normal or improved reactivity, the sepsis rate was 21% and mortality 2.1%. Of the 43 patients who had no improvement, the sepsis rate was 65% and the mortality 74%.

Our patient required three extra weeks of TPN to improve his skin reactivity and to restore body cell mass[9] and the most probable explanation for the initial failure of TPN in correcting the immune mechanisms and responsiveness was the existence of sepsis at the onset of hyperalimentation.[10]

In summary, we have presented a young male with severe Crohn's ileocolitis with marked weight loss and perineal fistulization who remained anergic after two weeks of TPN (45 KCal/Kgr/24 hours; N/KCal = 1/180) and bowel rest in spite of adequate weight gain and return to normal serum albumin and total protein levels. He required three additional weeks of TPN (50KCal/Kgr 24 hours; N/KCal = 1/200) to restore skin reactivity. Subsequent operative intervention revealed healing of his intraabdominal fistulae and he had an essentially uncomplicated postoperative course without infection. We believe serial skin testing is perhaps the most sensitive indicator of adequacy of treatment in TPN.

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# Paradoxical Embolism

## A Case Report and Brief Review of Literature

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**ABSTRACT—Paradoxical embolism following an episode of pulmonary embolism and resulting in bilateral femoral artery occlusion was diagnosed during life. Pulmonary hypertension was not evident at cardiac catheterization, but a small intraarterial left-to-right shunt was demonstrated. Paradoxical embolism should be considered in the differential diagnosis of arterial embolism for which there is no obvious source, particularly if there is co-existence of venous thrombosis and/or pulmonary embolism.**

Embolic occlusion caused by the passage of venous clot to the systemic arterial circulation was first defined as "paradoxical embolism" by Cohnheim in 1877.[1] Normally a venous thrombus cannot traverse the pulmonary capillaries and remains in the pulmonary artery or its branches. In the presence of an intra-cardiac communication and a right-to-left flow pattern, a venous thrombus may cross from the right heart to the left and embolize to a systemic artery. The typical clinical triad includes (1) venous thrombosis and/or pulmonary embolism; (2) an intra-cardiac communication that will permit a right-to-left shunt; and (3) arterial embolism without evidence of a source of embolus from the left side of the heart or the proximal arterial tree.[2]

In most cases[3-11] paradoxic embolism is established at post-mortem examination. The diagnosis is seldom made during life. In a review of 151 reported cases, only 21 were detected during life and in only 12 was the diagnosis documented by cardiac catheterization and angiography.[7, 8]

### Case Report

An 18-year-old white male was admitted complaining of right lower quadrant and periumbilical pain. Three weeks prior to admission he suffered a severe contusion and sprain of his right ankle. A cast was applied and remained in place for 2 weeks. Following removal of the cast, he was referred for physiotherapy. During the first 3 days of physiotherapy he noted mild chest discomfort and experienced some difficulty in breathing. On the fourth day of physiotherapy he complained of periumbilical abdominal pain which radiated to the right lower quadrant. He was admitted to the surgical service for evaluation. The patient had also noted anorexia and vomiting. Examination of the abdomen revealed right lower quadrant tenderness without spasm or rebound. The chest x-ray showed a normal sized heart with clear lung fields. Bowel sounds were hypoactive and rectal examination revealed tenderness of the right pararectal area. Examination of the extremities revealed stiffness of the right ankle. There was no evidence of phlebitis and no Homan's sign. A diagnosis of probable acute appendicitis was made and the patient underwent exploratory laparotomy. There was no evidence of acute appendicitis or inflammatory disease of the bowel and an incidental appendectomy was performed. Postoperatively the patient's temperature rose to 103°F. The post-operative chest x-ray showed consolidation of the right lower lobe. Arterial blood gases were: PO2 40mm Hg., pCO2 34.3mm Hg. Bicarbonate was 26.6 meq/L and the arterial pH was 7.46. The patient was treated with 40% oxygen by mask. On the third post-operative day his temperature again rose to 103°F. The pulse rate was 144/minute, and the respiration rate was 36/minute. He appeared anxious and diaphoretic.

Arterial blood gases were: pO2 35.2mm Hg., pCO2 30.7mm Hg. The bicarbonate was 20.7 meq/L and the arterial pH was 7.45. The hemoglobin oxygen saturation was 61.2%. The chest x-ray now showed right upper lobe and middle lobe consolidation. The next evening, he complained of bilateral thigh pain. Examination revealed hypothermia and cyanosis of the right calf and foot. Mottling was present to the mid-calf level. Pallor was evident in the remaining part of the right leg and all of the left leg was pale. There was complete absence of pulses in both legs. Emergency

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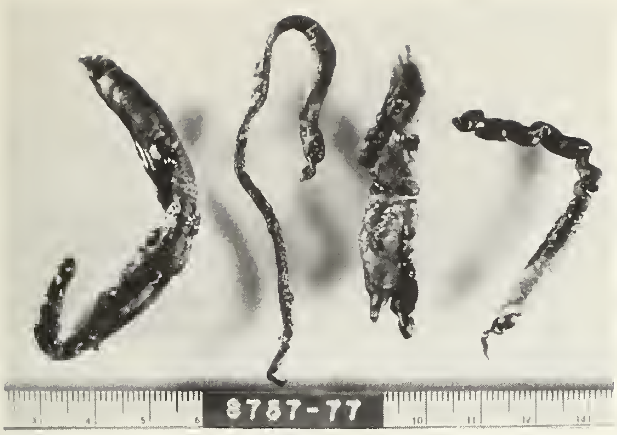

Figure 1
Venous Thrombus removed from femoral arteries showing mottled appearance and distinct linear markings on the surface (lines of Zahn).

arteriography was performed, showing bilateral femoral artery occlusion. The patient underwent bilateral femoral embolectomy and plication of the right superficial femoral vein. Pathologic study of the clot removed from the occluded arteries confirmed venous origin (Figure 1).

Following clinical stabilization, the patient underwent right heart catheterization on the first post-operative day. Physical examination at that time revealed a well developed, white male in no acute distress. Heart rate was 80/minute and regular. Respiratory rate was 18/minute. Blood pressure was 120/80mm of Hg. There was no jugular venous distention or abnormal venous pulsations. The liver was not enlarged and there was no pedal edema. The left ventricular impulse was felt in the 5th intercostal space medial to the mid-clavicular line. No thrills or abnormal pulsations were palpated. Pulmonary valve closure was not palpable. The first sound was normal. A grade II/VI ejection systolic murmur was heard at the second left intercostal space. The pulmonic component of the second sound was increased in intensity, widely split, but not fixed. There were no gallop rhythms. The lungs were normal to percussion and auscultation. CBC and urinalysis were normal. An echocardiogram demonstrated an increased right ventricular dimension of 3.6cm (normal 0.7-2.3cm). There was normal motion of the inter-ventricular septum and normal mitral and aortic valve motion. Right heart catheterization, pulmonary angiography and an oxygen saturation shunt study were performed. Pressures were recorded in the pulmonary capillary wedge position and from all the chambers of the right heart. All pressures were normal. An increase in oxygen saturation was noted between mid-right atrium and low right atrium, consistent with a secundum atrial septal defect. The calculated ratio of pulmonary blood flow to systemic blood flow was 1.7:1.

## Discussion

This patient presented with pulmonary embolus mimicking an acute abdomen. He then developed arterial embolization. The initial event was thrombophlebitis of the right leg causing embolus to the pulmonary artery with transient pulmonary hypertension and reversal of an intra-atrial shunt. The temporary reversal of the pre-existing shunt facilitated the passage of a thrombus, presumably arising in the lower extremity, to the left atrium and finally to the femoral arteries.

The sequellae of paradoxical embolism may be disastrous, particularly if cerebral or coronary arteries are occluded. The most important clue to diagnosis is the sequence of pulmonary embolism followed by systemic embolism. When systemic embolism occurs in temporal proximity to pulmonary embolism the following possibilities should be considered: (1) paradoxical embolism; (2) primary cardiomyopathy with mural thrombi in both sides of the heart; (3) acute myocardial infarction with mural thrombi in the left ventricle, occurring concurrently with pulmonary emboli from peripheral veins; (4) emboli from myxomas of both right and left atria; (5) emboli related to prosthetic replacement of both mitral (and/or aortic) and tricuspid valves; (6) emboli arising from infective endocarditis involving both left and right sided cardiac valves.

The *sine qua non* of paradoxical embolism is arterial occlusion due to emboli originating in the venous circulation. Arterial embolism is readily recognized when it involves an extremity. However, embolism should also be considered when myocardial infarction or cerebrovascular accident occur in a patient without the usual predisposing causes. In a review of eighty-two consecutive cases of peripheral arterial embolis,[12] the left side of the heart was the source of emboli in 94%. Mitral stenosis or atrial fibrillation was present in 55% of patients, and myocardial infarction was the underlying cause of thrombus formation in the left side of the heart in an additional 39%. Thus when arterial embolism occurs in the absence of mitral stenosis, atrial fibrillation or myocardial infarction, paradoxical embolism should be considered. A search should be made for the presence of concomitant venous thrombosis, or its sequella, pulmonary embolism. The secundum type of atrial septal defect is the most common congenital shunt present in adults.[13]

Shunt flow is predominently left to right, but frequently there is an associated small right to left shunt.[14] This has been attributed to streaming of venous blood from the inferior vena cava toward the region of the fossa ovalis and subsequently across the atrial septal defect. If venous thromboembolism occurs in a patient with an uncomplicated secundum atrial septal defect, there is a small but definite risk of paradoxical embolism.

Most reported cases of paradoxical embolism have not been associated with overt congenital heart disease. Rather, they have occurred in association with a patent foramen ovale. Thompson and Evans[15] found that a "pencil patent" foramen is found in 6% of unselected autopsies and a "probe patent" foramen in 29%. A patent foramen ovale presents no abnormalities by history, physical examination, electrocardiogram or chest roentgenogram since, under normal conditions, flow does not occur across the foramen.

Right to left shunting may occur under the following conditions: (1) right ventricular hypertension (typically secondary to acute or chronic pulmonary embolism or chronic obstructive lung disease); (2) right atrial hypertension (as in tricuspid atresia, stenosis, regurgitation and Ebstein's anomaly); (3) performance of Valsalva maneuver. Valsalva maneuver causes right atrial pressure to momentarily exceed left atrial pressure, reversing the normal intra-atrial pressure gradient, with a resultant right to left shunt across a transiently patent foramen ovale. Banas and associates[19] were able to show a right to left shunt across a surgically created minute atrial septal defect in dogs during the straining phase of the Valsalva maneuver. The Valsalva maneuver has been employed in the clinical diagnosis of paradoxical embolism to successfully document a transient right to left shunt.[17]

In patients with arterial embolism it may be prudent to perform a lung scan whether or not there are overt symptoms and signs of pulmonary embolism. A peripheral venogram may also be of diagnostic aid. Right and left heart catheterization and angiography should be considered in order to rule out atrial myxoma, mural thrombus, mitral stenosis, and intracardiac septal defects.[17] Catheter passage through a patent foramen ovale may be facilitated by introduction from a femoral vein. Indicator dilution curves from the right atrium, both before and after a Valsalva maneuver, are sensitive means of detection of very small shunts.

Since the venous thromboembolism is a recurrent disease,[18] if systemic embolism is found to be of venous origin measures to prevent recurrence are mandatory. If venous interruption is necessary, inferior venacaval ligation is preferred, since plication may still permit the passage of small venous emboli. The cardiac defect, usually a patent foramen ovale, does not require surgical closure. With rare exceptions, surgical closure of the cardiac defect should be based on shunt size, hemodynamics and clinical status, rather than solely on the occurrence of paradoxical embolism.[5]

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# Screening for Congenital Hypothyroidism in Connecticut

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Prevention of mental retardation is the major purpose of neonatal metabolic screening, which is an established public health activity. In Connecticut the State Health Department has been screening for phenylketonuria (PKU) and galactosemia since 1966 and 1969 respectively. In April, 1976, the program was expanded to include congenital hypothyroidism as part of a New England Regional Screening Network. This paper reports the experience in Connecticut with the first two years of screening.

### Physiological Basis for Screening

Recent advances in the understanding of neonatal thyroid function established the physiological basis for screening at birth. Good reviews of the subject are available,[1] [2] thus only pertinent information is summarized. Fetal hypothalamic-pituitary-thyroid axis functions autonomously under normal circumstances. Thus the thyroid function of the newborn is reflected by blood hormone concentration as maternal thyroid hormones do not cross the placenta. As in the adult, the fetus and the neonate produce thyroxine (T4) as the major product of the thyroid gland. T4 is converted to the hormone with greater metabolic potency—3,5,3 triiodothyronine (T3)—by beta ring deiodination. Alpha ring deiodination produces 3,3,5 triiodothyronine, a metabolically inactive substance referred to as reverse T3. The production of T4 by the thyroid gland is regulated by the thyroid-stimulating hormone (TSH) from the pituitary. By a negative feedback system T3 and T4 regulate TSH production.

The maximal production of thyroid hormone by the fetus is in the last trimester of pregnancy.[3] The T4 produced by the fetus is largely converted to the metabolically inactive reverse T3. A surge in TSH release occurs soon after birth and is followed by rapid increases in the concentration of T4 and T3 with the T4 being preferentially deiodinated to T3 rather than to reverse T3. This rapid increase in thyroid hormone concentration is related to the need to maintain body temperature in the extrauterine environment. These fluctuations in hormone concentrations are most pronounced in the first 48 to 72 hours and must be recognized in interpreting results of thyroid testing, including screening.

Thyroxine is the most easily measured and at this time the least expensive parameter of neonatal thyroid function. Greater than 99% of the total T4 is present in the blood bound to transport proteins chief among which is thyroxine-binding globulin (TBG). While the free T4 constitutes less than 0.1% of the total T4, it is in equilibrium with the bound T4 and reflects the thyroid hormone status more accurately than the total T4. Determination of the free T4 concentration is technically difficult but low values are accompanied by elevation in the TSH concentration provided the hypothalamic-pituitary axis is normal. Since the usefulness of total T4 as an indicator of hypothyroidism in the neonatal period is interfered with by a number of conditions that alter TBG concentration (prematurity, low birth weight, perinatal stress, congenital TBG deficiency, nephrosis, maternal estrogens), TSH measurement gives a more reliable estimation of the concentrations of the effective thyroid hormones (free T4 and T3) in the circulation.

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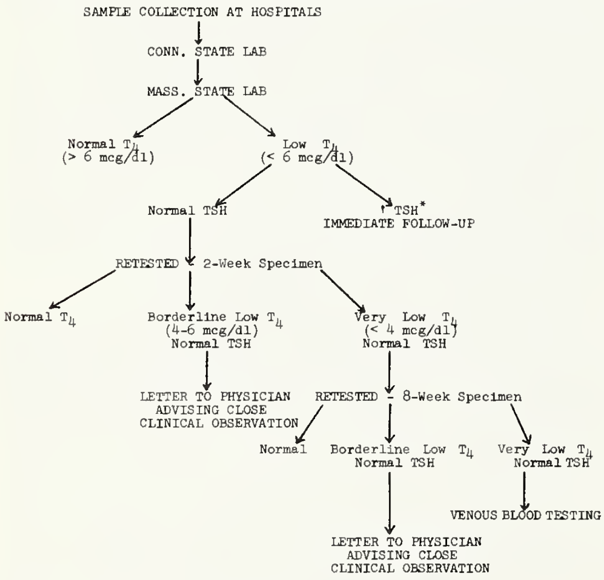
## Screening Program

Figure 1 is a schematic representation of the organization whereby samples of blood from newborn infants are collected, tested, and abnormalities followed through to a satisfactory conclusion. A capillary blood sample is collected on standard filter paper (Schleicher and Schuell) prior to discharge of the newborn from the hospital. These samples are mailed to the State Health Department in Hartford where after testing for PKU and galactosemia they are sent by van to the Massachusetts State Institute Laboratory, the centralized regional facility for hypothyroidism testing.[4] Total T4 concentration is measured by radioimmunoassay using automated techniques. Samples with low T4 concentration as defined by values less than 2 S.D. of mean of each day's tests (this is generally around < 6 mcg/dl) are selected for further testing. TSH concentration is measured on these samples at the Peter Bent Brigham Hospital Thyroid Unit. The details of this two-tiered method of identifying primary hypothyroidism have been described by Mitchell et al.[5]

Figure 1

Organization for Collection of Samples, Testing, and Follow-up


SAMPLE COLLECTION AT HOSPITALS
CONN. STATE LAB
MASS. STATE LAB
Normal $T_4$ (> 6 mcg/dl)
Low $T_4$ (< 6 mcg/dl)
Normal TSH
↑ TSH*
IMMEDIATE FOLLOW-UP
RETESTED - 2-Week Specimen
Normal $T_4$
Borderline Low $T_4$ (4-6 mcg/dl) Normal TSH
Very Low $T_4$ (< 4 mcg/dl) Normal TSH
LETTER TO PHYSICIAN ADVISING CLOSE CLINICAL OBSERVATION
RETESTED - 8-Week Specimen
Normal
Borderline Low $T_4$ Normal TSH
Very Low $T_4$ Normal TSH
VENOUS BLOOD TESTING
LETTER TO PHYSICIAN ADVISING CLOSE CLINICAL OBSERVATION

*Whenever TSH is elevated, immediate follow-up is made.

## Follow-up of Children with Abnormal Test Results

When low T4 is accompanied by an elevated TSH, primary hypothyroidism is presumed and arrangements for immediate follow-up are made by telephone. The child is usually examined by an endocrinologist and after drawing blood for confirmatory tests, treatment is begun with synthetic thyroxine (Snythyroid) at a dose of 25-50 mcg daily.

Most children with low T4 values do not have elevated TSH levels. While such results are not usually associated with pathological conditions, children with hypothyroidism secondary to TSH deficiency (i.e., failure of hypothalamic-pituitary axis function) and lowered concentration of TBG would be expected to have similar results. Since low TSH values cannot be differentiated from normal TSH values by techniques now available, follow-up testing of children with low T4 and normal TSH is required to differentiate those with significant problems from the majority of children who would be normal. Repeat testing is done using the blood filter paper sample routinely collected on all newborns in Connecticut at two weeks of age for PKU screening. Based on the screening experience in Quebec and in the region in the first year, abnormal test results from the second sample are now followed up differently from the first one. Elevated TSH is always followed up immediately. When the TSH is not elevated, only those with T4 values < 4 mcg/dl have repeat testing at eight weeks of age. When the T4 is between 4 and 6 mcg/dl repeat testing is not done, but letters are sent to physicians caring for these infants advising close observation. When the abnormality persists on the third test, (i.e., T4 < 4 mcg/dl) arrangements are made for further examination and investigation by an endocrinologist.

## Developmental Testing

Developmental testing of all children with congenital hypothyroidism diagnosed through the regional screening program is being carried out at yearly intervals with suitable controls in order to assess the effect of instituting early treatment. In Connecticut the children are being examined at home and in clinics by child developmental consultants from the State Health Department and the Yale Child Study Center, using Bayley Scales, Stanford-Binet Scales, and questionnaires designed to study significant medical and social variables.

In order to establish uniform standards in diagnosis, treatment, and evaluation throughout the region, guidelines have been established by a collaborative group of pediatric endocrinologists from the New England region with Dr. Robert Klein as the coordinator. In Connecticut the screening committee of the Hezekiah Beardsley Chapter of The American Academy of Pediatrics acts in an advisory capacity to the State Health Department in matters relating to newborn screening.

## Results

Of the 71,798 children screened, 17 infants have been found to have primary hypothyroidism. Two cases of primary hypothyroidism were known to have been missed by the program. Based on these figures the incidence of congenital hypothyroidism in Connecticut is 1:3778 births. No cases of secondary hypothyroidism have yet been detected. Four infants have been identified as having an inherited deficiency of TBG (1:17,949 births). In only three of the 17 infants was hypothyroidism clinically manifested prior to the availability of the laboratory report. Of the 19 known cases in the state there were 14 females, 4 males, and one male pseudohermaphrodite.

There was a wide spectrum of clinical manifestations ranging from obviously affected infants to infants with no clinical and radiological abnormalities. One child was suspected of having the condition on the first day of life while another child had jaundice, lethargy, and feeding difficulties by the eighth day. One child whose condition was diagnosed by the screening program was seen on the nineteenth day of life and found to be obviously cretinoid with a large tongue, mottled skin, hoarse cry, and other features of congenital hypothyroidism in association with a retarded bone maturation. Only two children have had palpable goiters. Six were diagnosed as athyrotic (thyroid tissue not visualized on 99m technetium pertechnetate scanning), three had dysgenetic glands (abnormal size and location of the gland), and five had proved dyshormonogenesis (increased uptake of technetium by a normally-located enlarged gland). Two infants with congenital nephrosis appear to have had compensated hypothyroidism secondary to excessive urinary loss of iodine and thyroixine.[6] In both cases the initial screening showed a "low" T4 without elevated TSH and, in both, TSH became significantly elevated by three weeks of life. Infants with athyrosis generally tended to have more severe clinical manifestations than those with dyshormonogenesis. Diagnostic studies have not been completed in three infants.

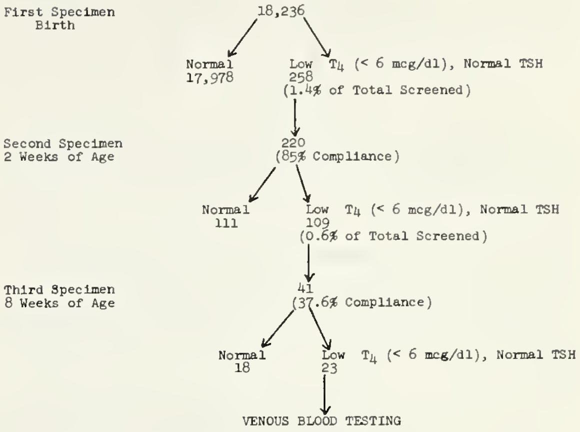
The mean age at inception of therapy in those diagnosed by the screening program (excluding those on whom clinical diagnosis was made and those with hypothyroidism secondary to congenital nehprosis) was 24 days (median 22 days, range 17-35 days)

Since changes have been made recently in the follow-up protocol, the rates of low T4 values (i.e., <6 mcg/dl) without elevated TSH and compliance of testing are best represented by a period of six months from July to December, 1977 (Figure 2). The first sample of blood was collected on almost 100% of the children born in hospitals in the state. During the six months from July to December, 1977, 18,236 children had their first blood sample tested of whom 258 (1.4%) had low concentrations without elevation of TSH. Of these, 220 (85%) had a second-week blood specimen tested. Requests for a third blood sample to be collected at eight weeks of age were made on 109 of these children who continued to have a low T4 without TSH elevation. This was the first non-routine blood collection and was requested in 0.6% of the total screened. Blood testing was done through the screening program in 41 of the 109 (37.6%) but it is likely that at least some had testing done outside the centralized system. Twenty-three of those tested (0.2%) of the total screened) continued to show low T4 and were referred to an endocrinologist for a definitive work-up. The only abnormality detected in these children has been low TBG concentration. Most of them had normal thyroid function when tested with venous blood samples at 12 to 16 weeks of age.

Figure 2

Non-Hypothyroid Infants Tested and Rate of Compliance

July - December, 1977


First Specimen Birth
18,236
Normal 17,978
Low $T_4$ (< 6 mcg/dl), Normal TSH 258 (1.4% of Total Screened)
Second Specimen 2 Weeks of Age
220 (85% Compliance)
Normal 111
Low $T_4$ (< 6 mcg/dl), Normal TSH 109 (0.6% of Total Screened)
Third Specimen 8 Weeks of Age
41 (37.6% Compliance)
Normal 18
Low $T_4$ (< 6 mcg/dl), Normal TSH 23
VENOUS BLOOD TESTING

The results of the psychological testing, which will not be completed until each child reaches the age of six, are not available at the time of this report.

## Cost of Screening

The screening cost for the approximately 36,000 infants born in Connecticut is around $70,000 per year. This figure includes the costs of detection and when eligible for coverage under the Services for Handicapped Children, laboratory, radiological, and developmental testing, clinic visits, and support to families including the services of social workers. It does not cover the cost of confirmatory testing on those ineligible for Services for Handicapped Children.

## Comments

Biochemical methods are needed to detect disorders in which mental retardation caused by a metabolic abnormality precedes the appearance of obvious clinical signs. Congenital hypothyroidism, which is one such disorder, is also sporadic and is not associated with any reliable prenatal or natal markers of the condition. Thus, the most efficient method of preventing the costly and tragic outcome of the untreated condition is early neonatal diagnosis and treatment. The urgency for early treatment is underlined by studies suggesting improved outcome for those whose therapy is begun prior to three months of age.[7] [8] The benefits of beginning treatment earlier than three months are yet to be defined and will be assessed as part of this program. Preliminary results from Quebec one year after initiating early treatment in cases detected by biochemical screening indicate very favorable outcomes[9] but more data is required before a final conclusion can be reached.

The program in Connecticut is in compliance with the standards for genetic screening published by The National Academy of Science and those for neonatal hypothyroidism screening by The American Academy of Pediatrics.[10] The experience in the program indicates the feasibility of identifying and treating neonates at risk for mental retardation from thyroid hormone deprivation prior to one month of age.

However, as would be expected of any new program, problems were encountered. An efficient screening method should be sensitive enough to diagnose all infants at risk for the disorder but yet be specific enough to avoid needlessly testing a large number of normal infants in order to confirm the abnormality in a few individuals. The program failed to detect hypothyroidism in two infants in the state. These were the result of accidental errors in the operational aspects of the program which are unlikely to recur and the screening method utilized could be considered to be sufficiently sensitive.

Another problem arose from lack of specificity of total T4 concentration in identifying those with congenital hypothyroidism. The total T4 concentration is often depressed without an identifiable cause. It is transiently depressed in infants with prematurity, low birth weight, acute neonatal illness, and sustained low levels as seen in inherited deficiency of TBG. The measurement of TSH, which is considerably more difficult and expensive, has been utilized to enhance specificity. The specificity in the program is further enhanced in Connecticut by testing the second-week blood specimen which is routinely available. Connecticut is the only New England state where routine second-week blood specimens are required for identification of children with PKU. Utilizing this specimen, the number of children who required a non-routine procedure for confirmation of diagnosis was approximately 0.6% of the total screened. The major problem with non-routine blood collection for detection of conditions associated with mental retardation is parental anxiety. While the figure of 0.6% of the total screened is acceptable by conventional standards, the failure to identify any significant problems within this group makes one wonder about the benefit of repeat testing as compared to careful clinical follow-up provided this was uniformly available. However, given the risk of secondary (pituitary) hypothyroidism in the population on whom this blood specimen is requested, it is possibly prudent to continue testing until more data is available.

Recognition of the different nature of neonatal hypothyroidism and the methods used to identify it, as compared to the other two metabolic conditions for which screening is performed in the state, is important in understanding the program. Unlike testing for PKU and galactosemia, sensitive radioimmunoassay techniques are utilized to measure thyroid hormone concentrations. Poor labeling of radioactive iodine used in the measurement of total T4 resulted in an artificial lowering of the calculated thyroxine values with consequent increased recall for repeat testing. Such problems are likely to recur until further refinement of the techniques becomes available.

Testing is done at a time of rapid change in thyroid function and hence the findings in the first few days or weeks of life do not always accurately predict the thyroid functional status later on in infancy and childhood. Infants with transient hypothyroidism in the neonatal period have been described. The thyroid functional status of children diagnosed as having congenital hypothyroidism by the New England regional program is to be retested after two years of age to confirm the need for lifelong treatment. The converse situation is also likely to be a problem as some children with normal findings in the neonatal period could develop the disorder later.[11] However, the index of suspicion of physicians is likely to be reduced on the basis of a normal test result at one point in time. An awareness of these possibilities by physicians dealing with infants and children would be an important component of a successful program.

The degree and duration of thyroid hormone deprivation are likely to affect eventual mental prognosis. Screening alters the duration of deprivation. The degree of deprivation depends upon the nature of the thyroid disorder[12] (children with dyshormonogenesis are often less affected than those with athyrosis) and on the supply of thyroid hormones to the children from exogenous sources. It has been shown that breast milk selectively concentrates thyroid hormones and possibly has some compensatory effect on thyroid hormone deprivation.[13] Studies have shown better mental prognosis for breast-fed infants with congenital hypothyroidism as compared to bottle-fed infants.[14] Thus, children diagnosed by the screening program are not all equally at risk for mental retardation.

It is likely that the demonstrated ability to start treating congenital hypothyroidism by three to four weeks of age will prevent gross mental retardation which is usually associated with this condition. The cost of maintaining a retarded individual in society is estimated to be $12,000 per year by the Office of Mental Retardation of the state. It has been calculated that prevention by screening would be less costly to society than supporting retarded individuals throughout their lives. Ethical and emotional factors associated with mental retardation and its alleviation by prevention are factors which also have to be considered when studying the cost-benefit issue.

The regional organization of the program and the cooperation between institutions in the state (State Health Department, Yale University School of Medicine, Newington Children's Hospital, the University of Connecticut. and The American Academy of Pediatrics) in carrying out the program are also noteworthy features.

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# The Physical Development of the Young Athlete and Competitive Stress

RICHARD V. WORRELL, M.D.

**ABSTRACT—A knowledge of growth and maturation of the skeleton is of value to physicians and others involved in the care of young athletes. The three phases of skeletal maturation extend from the intra-uterine environment to puberty. Bones form by means of intramembranous or enchondral ossification. Primitive muscle tissue which is often associated with cartilage precursors of bone, can be identified as early as the fifth week in utero. All children involved in competitive sports should be evaluated with reference to growth, maturation and coordination. Early recognition of injuries in young athletes is important. Of great concern are injuries to the growth (epiphyseal) plates.**

### Physical Maturation

Persons involved in the training and treatment of young athletes should have some knowledge of the growth and maturation of the skeleton. Acheson[1] states that "in the skeleton of the healthy child the two processes—growth, or the creation of new cells and tissues, and maturation, or the subsequent consolidation of the tissues into permanent form—proceed pari passu, the one with the other."

Skeletal maturation can be divided into three phases.[1] The first phase occurs in utero. During this phase there is almost complete ossification of the diaphyseal portions of long and short bones. During the second phase, which starts just before birth, osteogenesis occurs in the area of the growth plates of the long and short bones of the appendicular skeleton. This phase is completed by puberty. In the final phase the growth plates cease to function and fusion of the epiphyses with the diaphyses occurs. Several factors influence skeletal maturation. Acheson[1] divides these factors into those which are intrinsic and those which are extrinsic. Among the intrinsic factors are those related to the sex of the individual. Generally speaking, females mature at a faster rate than males. Most studies seem to indicate that males are about three years behind females in maturation. Other intrinsic factors are the genetic and hormonal factors. Among extrinsic factors are those related to health, nutrition and the environment.

### Active Growth Centers and Ossification

Bone formation always occurs in a pre-existing connective tissue. The process by which bone is formed directly from primitive connective tissue or periosteum is called intramembranous ossification. When bone forms in pre-existing cartilage, the process is called enchondral ossification. In the embryo the cartilaginous precursor of the skeleton is present by the sixth week. Vascular invasion of the cartilage which will become long bones occurs from a primitive periosteal cuff at about 8 weeks. This vascular invasion of cartilage results in bone formation giving rise to the primary centers of ossification which are destined to become the diaphyses of the long bones. Secondary centers of ossification occur at the ends of long bones. These centers of ossification are destined to become the epiphyses. Most of the secondary centers of ossification appear at birth to 5 years of age. Some appear at about the time of

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puberty (traction epiphyses). Enchondral ossification occurs in most of these centers until about 12 years in girls and 15 years is boys.[2]

There are three types of epiphyses i.e. pressure, traction and atavistic epiphyses (Figure 1). The pressure epiphysis is located at the site of an articulation 3.g. the head of the femur. The traction epiphysis appears at about the time of puberty. They are located at the sites of attachment of certain tendons e.g. the trochanters of the femur. Atavistic epiphyses represent what were once independent bones which during the course of evolutionary development, have become parts of other bones e.g. the coracoid process of the scapula.

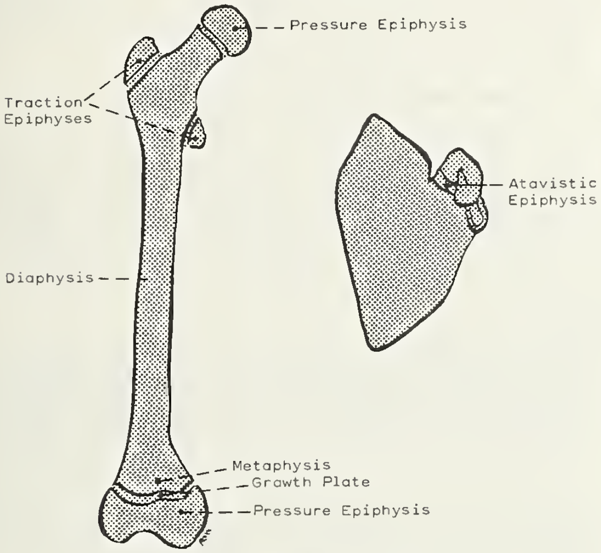

Figure 1
The three types of epiphyses.

The process of enchondral ossification which occurs at the growth plates of long and short bones, is responsible for the growth in length of these bones. The growth plates (epiphyseal plates) are cartilaginous discs located between the diaphysis and epiphysis of long bones. The portion of the diaphysis which borders on the growth plate is called the metaphysis. Rang[3] divides the growth plate into three zones i.e. zone of growth, zone of cartilage transformation and zone of ossification (Figure 2). The zone of ossification lies adjacent to the metaphysis. In the zone of growth germinal cells divide transversely and form columns or palisades of chondrocytes. In the zone of cartilage transformation the chondrocytes accumulate increasing amounts of glycogen and hypertrophy. As the chondrocytes get larger, calcification of the chondroid matrix occurs.

The calcification of the matrix interferes with the nutrition of the chondrocytes leading to their degeneration. In the zone of ossification calcified chondroid bars are invaded by blood vessels from the metaphysis. Bone forming cells (osteoblasts) subsequently form bone on the calcified chondroid bars. Finally, there is gradual resorption of the calcified chondroid.

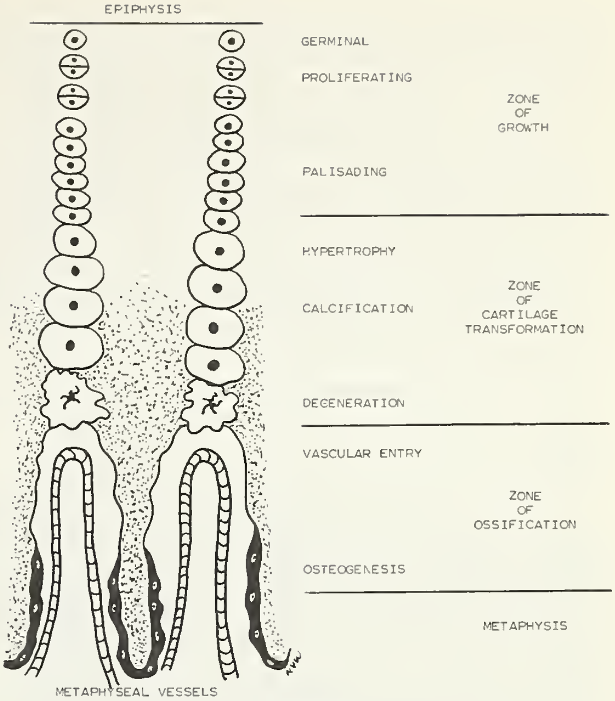

Figure 2
The growth plate (after Rang).

### The Development of Skeletal Muscle

In the embryo mesoderm which surrounds the cartilaginous precursors of bone become muscles. Muscle formation may, however, be independent of bone formation. Primitive muscle tissue can be identified as early as the fifth week in utero. Nerves can also be identified with developing muscles. The earliest spontaneous joint movements occur during the twelfth week in the fetus. The number of fibers per muscle is fixed before birth. Muscle growth after birth relates to increase in fiber size.

### The Ability of a Child to Weather the Stress of Athletics

Problems related to growth and development occur most often in athletes between the ages of 5 and 18 years. By age 18 years in males, most of the growth plates in the long and short bones are obliterated as epiphyses fuse with diaphyses and growth ceases. This process occurs at an earlier age in females. It should be noted that epiphyseal centers of the vertebrae, ribs, and shoulder and pelvic girdles first appear at puberty then are obliterated by fusion at about age 25 years.

Larson[4] states that "recommendations by the physician regarding athletic competition for children must take into account a wide variation in growth, maturity and coordination. Abnormalities of skeletal development or chronic disorders should be evaluated on an individual basis with consideration of what activities can be safely tolerated." He further states that "injuries occurring to the adolescent are not more prevalent—indeed, less so—than in the older athlete."

Of great concern to physicians involved in the treatment of young athletes are epiphyseal injuries. Premature growth arrest giving rise to shortening and/or deformity of the involved bone represents a real danger with many of these injuries. Nicholas[5] states that "in the adolescent certain anatomic considerations are important in any study of the effects of injury. Unlike the adult, weakness is most evident at the tendon insertion to traction epiphyses. Moreover the metaphyseal portion of the pressure type of epiphysis is weaker than the muscle-tendon unit."

Salter and Harris[6] have provided a useful classification of fractures involving the epiphyseal (growth) plates (Figure 3). The Type I fracture passes through the epiphyseal plate. The Type II fracture passes through the epiphyseal plate and includes a triangular fragment of bone from the edge of the metaphysis. The Type III fracture passes transversely through the epiphysis then passes through the epiphyseal plate. The Type IV fracture passes transversely through the epiphysis, epiphyseal plate and metaphysis. The Type V fracture represents a crush injury of the epiphyseal plate. Fractures which involve the zone of growth which contains the germinal cells of the epiphyseal (growth) plate, usually result in premature growth arrest. In most Type I fractures the fracture line passes through the area of chondrocyte hypertrophy in the zone of cartilage transformation. Therefore, the chances of premature growth arrest after adequate reduction of the fracture are least with Type I fractures and greatest with Type V fractures.

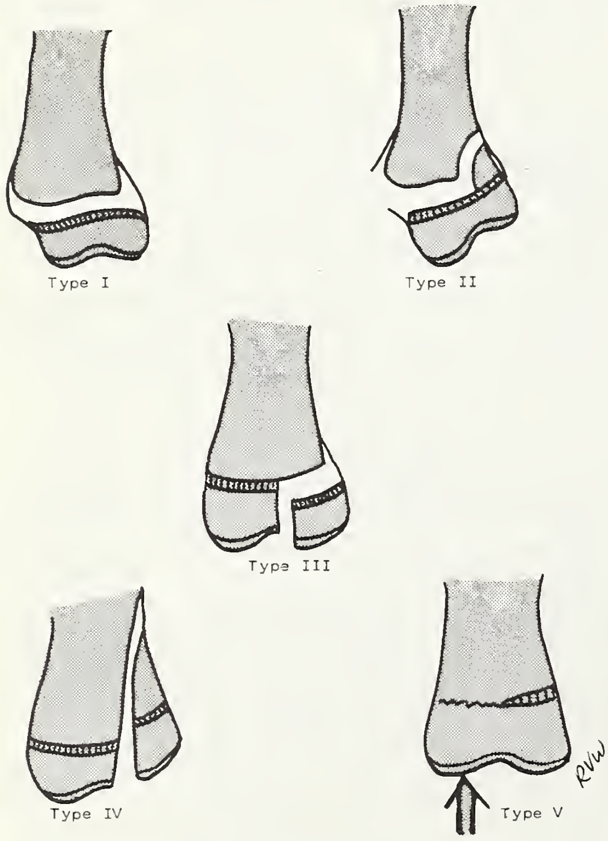

Figure 3
The Salter-Harris classification of fractures involving the epiphyseal (growth) plate.

Injury to the medial epicondylar epiphysis of the elbow can occur in children who pitch in little league baseball.[7] This condition has been called "little leaguer's elbow."[8] DeHaven and Evarts[9] recommend limiting the number of pitches thrown by any one player per game plus three days of rest between games. Traumatic epiphysitis can also involve the tibial tubercle, os calcis and vertebrae.

There are developmental problems which may affect the performance of young athletes. Many of these conditions involve the knee joint[10] e.g. osteochondritis dissecans, discoid menisci, Osgood-Schlatter Disease, chondromalacia and patellar tendinitis. Early recognition of these disorders is important in order to minimize damage to the knee joint.

In summary, all children involved in competitive sports should be evaluated with reference to growth, maturity and coordination. A complete physical examination should be performed with special emphasis on the detection of any developmental abnormalities that could affect performance or lead to injuries. Early recognition of injuries and prompt appropriate treatment are essential for the well-being of young athletes.

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# Gonorrhea

## Center for Disease Control Recommended Treatment Schedules

*Note: Physicians are cautioned to use no less than the recommended dosages of antibiotics.*

### Uncomplicated Gonococcal Infections in Men and Women

Drug Regimens of Choice

Aqueous procaine penicillin G (APPG) 4.8 million units injected intramuscularly at two sites, with 1.0 g of probenecid by mouth.

or

Tetracycline hydrochloride* 0.5 g by mouth 4 times a day for 5 days (total dosage 10.0 g). Other tetracyclines are not more effective than tetracycline hydrochloride. All tetracyclines are ineffective as a single-dose therapy.

or

Ampicillin 3.5 g, or amoxicillin 3.0 g, either with 1 g probenecid by mouth. Evidence shows that these regimens are slightly less effective than the other recommended regimens.

Patients who are allergic to the penicillins or probenecid should be treated with oral tetracycline as above. Patients who cannot tolerate tetracycline may be treated with spectinomycin hydrochloride 2.0 g in one intramuscular injection.

Special Considerations

- Single-dose treatment is preferred in patients who are unlikely to complete the multiple-dose tetracycline regimen.
- The APPG regimen is preferred in men with anorectal infection.
- Pharyngeal infection is difficult to treat; high failure rates have been reported with ampicillin and spectinomycin.
- Tetracycline treatment results in fewer cases of postgonococcal urethritis in men.
- Tetracycline may eliminate coexisting chlamydial infections in men and women.
- Patients with incubating syphilis (seronegative, without clinical signs of syphilis) are likely to be cured by all the above regimens except spectinomycin. All patients should have a serologic test for syphilis at the time of diagnosis.
- Patients with gonorrhea who also have syphilis or are established contacts to syphilis should be given additional treatment appropriate to the stage of syphilis.

Treatment of Sexual Partners

Men and women exposed to gonorrhea should be examined, cultured and treated at once with one of the regimens above.

Followup

Followup cultures should be obtained from the infected site(s) 3-7 days after completion of treatment. Cultures should be obtained from the anal canal of all women who have been treated for gonorrhea.

Treatment Failures

The patient who fails therapy with penicillin, ampicillin, amoxicillin, or tetracycline should be treated with 2.0 g of spectinomycin intramuscularly.

Most recurrent infections after treatment with the recommended schedules are due to *reinfection* and indicate a need for improved contact tracing and patient education. Since infection by penicillinase (β-lactamase)-producing *Neisseria gonorrhoeae* is a cause of treatment failure, posttreatment isolates should be tested for penicillinase production.

Not Recommended

Although long-acting forms of penicillin (such as benzathine penicillin G) are effective in syphilotherapy, they have NO place in the treatment of gonorrhea. Oral penicillin preparations such as

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*Food and some dairy products interfere with absorption. Oral forms of tetracycline should be given 1 hour before or 2 hours after meals.

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*U.S. Department of Health, Education, and Welfare; Public Health Service Center for Disease Control, Atlanta, Georgia.*

penicillin V are not recommended for the treatment of gonococcal infection.

### Penicillinase-Producing *Neisseria Gonorrhoeae* (PPNG)

Patients with uncomplicated PPNG infections and their sexual contacts should receive spectinomycin 2.0 g intramuscularly in a single injection. Because gonococci are very rarely resistant to spectinomycin and reinfection is the most common cause of treatment failure, patients with positive cultures after spectinomycin therapy should be re-treated with the same dose.

A PPNG isolate that is resistant to spectinomycin may be treated with cefoxitin 2.0 g in a single intramuscular injection, with probenecid 1.0 g by mouth.

### Treatment in Pregnancy

All pregnant women should have endocervical cultures for gonococci as an integral part of the prenatal care at the time of the first visit. A second culture late in the third trimester should be obtained from women at high risk for gonococcal infection.

Drug regimens of choice are APPG, ampicillin or amoxicillin, each with probenecid as described above.

Women who are allergic to penicillin or probenecid should be treated with spectinomycin.

Refer to the sections on acute salpingitis and disseminated gonococcal infections for the treatment of these conditions during pregnancy. Tetracycline should not be used in pregnant women because of potential toxic effects for mother and fetus.

### Acute Salpingitis (Pelvic Inflammatory Disease)

There are no reliable clinical criteria on which to distinguish gonococcal from nongonococcal salpingitis. Endocervical cultures for *N. gonorrhoeae* are essential. Therapy should be initiated immediately.

A. Hospitalization should be strongly considered in these situations:

   1. Uncertain diagnosis, in which surgical emergencies such as appendicitis and ectopic pregnancy must be excluded.
   2. Suspicion of pelvic abscess.
   3. Severely ill patients.
   4. Pregnancy.
   5. Inability of the patient to follow or tolerate an outpatient regimen.
   6. Failure to respond to outpatient therapy.

B. Antimicrobial Agents

Outpatients

Tetracycline* 0.5 g taken orally 4 times a day for 10 days. This regimen should not be used for pregnant patients.

or

APPG 4.8 million units intramuscularly, ampicillin 3.5 g or amoxicillin 3.0 g each with probenecid 1.0 g. Either regimen is followed by ampicillin 0.5 g or amoxicillin 0.5 g orally 4 times a day for 10 days.

Hospitalized patients

Aqueous crystalline penicillin G 20 million units given intravenously each day until improvement occurs, followed by ampicillin 0.5 g orally 4 times a day to complete 10 days of therapy.

or

Tetracycline* 0.25 g given intravenously 4 times a day until improvement occurs, followed by 0.5 g orally 4 times a day to complete 10 days of therapy. This regimen should not be used for pregnant women. The dosage may have to be adjusted if renal function is depressed.

Since optimal therapy for hospitalized patients has not been established, other antibiotics in addition to penicillin are frequently used.

C. Special Considerations

- Failure of the patient to improve on the recommended regimens does not indicate the need for stepwise additional antibiotics but requires clinical reassessment.
- The intrauterine device is a risk factor for the development of pelvic inflammatory disease. The effect of removing an intrauterine device on the response of acute salpingitis to antimicrobial therapy and on the risk of recurrent salpingitis is unknown.
- Adequate treatment of women with acute salpingitis must include examination and appropriate treatment of their sex partners because of their high prevalence of nonsymptomatic urethral infection. Failure to treat sex partners is a major cause of recurrent gonococcal salpingitis.
- Followup of patients with acute salpingitis is essential during and after treatment. All patients should be recultured for *N. gonorrhoeae* after treatment.

### Acute Epididymitis

Acute epididymitis can be caused by *N. gonorrhoeae, Chlamydia* or other organisms. If gonococci are demonstrated by Gram stain or culture of urethral secretions, treatment should be:

APPG 4.8 million units, ampicillin 3.5 g or amoxicillin 3.0 g, each with probenecid 1.0 g. Either regimen is followed by ampicillin 0.5 g or amoxicillin 0.5 g orally 4 times a day for 10 days.

or

Tetracycline* 0.5 g orally 4 times a day for 10 days.

If gonococci are not demonstrated, the above tetracycline regimen should be used.

### Disseminated Gonococcal Infection

A. Equally effective treatment schedules in the arthritis-dermatitis syndrome include:

Ampicillin 3.5 g or amoxicillin 3.0 g orally, each with probenecid 1.0 g, followed by ampicillin 0.5 g or amoxicillin 0.5 g 4 times a day orally for 7 days.

or

Tetracycline* 0.5 g orally 4 times a day for 7 days. Tetracycline should not be used for complicated gonococcal infection in pregnant women.

or

Spectinomycin 2.0 g intramuscularly twice a day for 3 days (treatment of choice for disseminated infections caused by PPNG).

or

Erythromycin 0.5 g orally 4 times a day for 7 days.

or

Aqueous crystalline penicillin G 10 million units intravenously per day until improvement occurs, followed by ampicillin 0.5 g 4 times a day to complete 7 days of antibiotic treatment.

B. Special Considerations

- Hospitalization is indicated in patients who may be unreliable, have uncertain diagnosis, or have purulent joint effusions or other complications.
- Open drainage of joints other than the hip is not indicated.
- Intra-articular injection of antibiotics is unnecessary.

C. Meningitis and endocarditis caused by the gonococcus require high-dose intravenous penicillin therapy. In penicillin-allergic patients with endocarditis, desensitization and administration of penicillin is indicated; chloramphenicol may be used in penicillin-allergic patients with meningitis.

### Gonococcal Infections in Pediatric Patients

With gonococcal infections in children beyond the newborn period the possibility of sexual abuse must be considered. Genital, anal and pharyngeal cultures should be obtained from all patients before antibiotic treatment. Appropriate cultures should be obtained from individuals who have had contact with the child.

### Prevention of Gonococcal Ophthalmia

When required by State legislation or indicated by local epidemiologic considerations, effective and acceptable regimens for prophylaxis of neonatal gonococcal ophthalmia include:

Ophthalmic ointment or drops containing tetracycline or erythromycin.

or

One percent silver nitrate solution.

Special Considerations

- Bacitracin is not recommended.
- The value of irrigation after application of silver nitrate is unknown.

### Management of Infants Born to Mothers with Gonococcal Infection

The infant born to a mother with gonorrhea is at high risk of infection and requires treatment with a single intravenous or intramuscular injection of aqueous crystalline penicillin G 50,000 units to full-term infants or 20,000 units to low-birth-weight infants. Topical prophylaxis for neonatal ophthalmia is not adequate treatment. Clinical illness requires additional treatment.

### Neonatal Disease

A. Gonococcal Ophthalmia: Patients should be hospitalized and isolated for 24 hours after initiation of treatment. Untreated gonococcal ophthalmia is highly contagious. Aqueous crystalline penicillin G 50,000 units/kg/day in 2 doses intravenously should be administered for 7 days. Saline irrigation of the eyes should be performed as needed. Topical antibiotic preparations alone are not sufficient or required when appropriate systemic antibiotic therapy is given.

B. Complicated Infection: Patients with arthritis and septicemia should be hospitalized and treated with aqueous crystalline penicillin G 75,000 to 100,000 units/kg/day intravenously in 2 or 3 divided doses for 7 days. Meningitis should be treated with aqueous crystalline penicillin G 100,000 units/kg/day, divided into 3 or 4 intravenous doses, and continued for at least 10 days.

### Childhood Disease

Children who weigh 100 lbs. (45 kg) or more should receive adult regimens. Children who weigh less than 100 lbs. should be treated as follows:

Uncomplicated Disease

Uncomplicated vulvovaginitis, urethritis, proctitis or pharyngitis can be treated at one visit with:

Amoxicillin 50 mg/kg orally with probenecid 25 mg/kg (maximum 1.0 g).

or

Aqueous procaine penicillin G 100,000 units/kg intramuscularly plus probenecid 25 mg/kg (maximum 1.0 g).

### Special Considerations

- Topical and/or systemic estrogen therapy are of no benefit in vulvovaginitis.
- Long-acting penicillins, such as benzathine penicillin G, are not effective.
- All patients should have followup cultures and the source of infection should be identified, examined and treated.

### Gonococcal Ophthalmia

Ophthalmia in children is treated as in neonates but the dose of penicillin is increased to 100,000 units/kg/day intravenously.

### Complicated Infections

Patients with peritonitis or arthritis require hospitalization and treatment with aqueous crystalline penicillin G, 100,000 units/kg/day intravenously for 7 days. Aqueous crystalline penicillin G 250,000 units/kg/day intravenously in 6 divided doses for at least 10 days is recommended for meningitis.

### Allergy to Penicillins

Children who are allergic to penicillins should be treated with spectinomycin 40 mg/kg intramuscularly. Children older than 8 years may be treated with tetracycline 40 mg/kg/day orally in 4 divided doses for 5 days. For treatment of complicated disease, the alternative regimens recommended for adults may be used in appropriate pediatric dosages.

These recommendations were established after deliberation with these therapy consultants:

Harold C. Neu, M.D., College of Physicians and Surgeons, Columbia University; Erwin H. Braff, M.D., San Francisco Department of Public Health; Gary Cunningham, M.D., Southwestern Medical School, Dallas; King K. Holmes, M.D., Ph.D., USPHS Hospital, Seattle; Franklyn Judson, M.D., Department of Health and Hospitals, Denver; William McCormack, M.D., State Laboratory Institute, Boston; Edwin M. Mears, Jr., M.D., New England Medical Center, Boston; John D. Nelson, M.D., Southwestern Medical School, Dallas; Morton Nelson, M.D., Orange County, California; Suzanne M. Sgroi, M.D., Suffield, Conn.; Frederick Sparling, M.D., School of Medicine, The University of North Carolina, Chapel Hill; Lt. Col. Edmund C. Tramont, Walter Reed Army Medical Center, Washington, D.C.

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# Child Abuse and Neglect: The Hospital's Expanding Role in Prevention, Identification and Management

(Third of Three Parts)

DAVID L. KERNS, M.D., JANE CAVANAUGH, M.A.
AND BENJAMIN C. BERLINER, M.D.

**ABSTRACT—The magnitude and complexity of child abuse and neglect justify a full commitment by hospitals and their personnel to contemporary program development for prevention, diagnosis and management. This paper discusses the challenges to program development such as funding, in-kind manpower, territoriality and confidentiality and presents the spectrum of potential hospital involvement, including primary prevention, secondary prevention, education and child and family advocacy.**

### Issues in Program Development

#### Funding

Financial resources to support new personnel are crucial for child protection program development. While volunteers and "in-kind" contributions from professionals play a large role, particularly at the beginning of new programs, revenue for full-time salaried staff members must be generated if community-based programs are going to have a significant long-term impact on child abuse and neglect. It is therefore necessary to examine the variety of potential funding sources in Connecticut, with particular attention to how each could most likely contribute to overall funding strategy.

*Direct Federal Sources*—In 1974, the National Center on Child Abuse and Neglect (NCCAN) was established by the federal Child Abuse Prevention and Treatment Act (PL-93-247). NCCAN is an HEW subsidiary within the Children's Bureau under the Administration for Children, Youth and Families. Funds have been made available for large research and demonstration projects. Categorical grants have strictly defined project requirements and have proven to be highly competitive. Of approximately 360 applications for these resources in 1975, only 17 were funded nationally. In view of the highly competitive nature of these grants, it is quite unlikely that community agencies would succeed in acquiring program funds from NCCAN. The establishment of the NCCAN grants program has had a negative effect within the Administration for Children, Youth and Families in that other grant programs, e.g., "Child Welfare Grants" now specifically exclude child abuse and neglect from their funding priorities.

The National Institute of Mental Health (NIMH) is another direct federal resource. NIMH grants, like those from NCCAN, are categorical and highly competitive, putting them out of the reach of most community programs. Considering the time and energy required for the preparation of federal grant applications, one should regard these direct federal sources as "long shots" and not rely on them for community-level program development.

*State Sources*—The Connecticut Department of Children and Youth Services (DCYS) is the mandated

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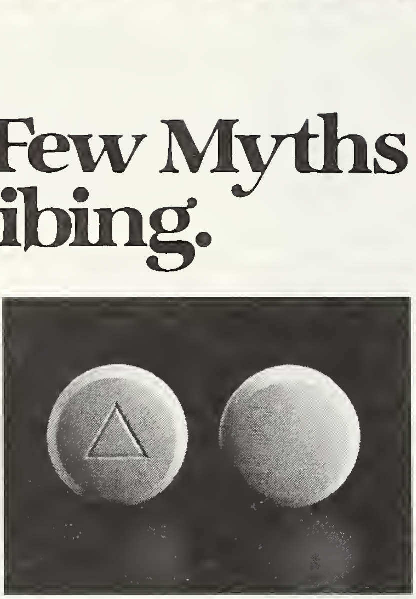
# The Maker

## Examining a Few Myths About Prescribing.



Increasing pressure is being put on the practicing physician to prescribe drugs generically. You are told that brand-name products are universally "expensive" and generic versions are relatively "cheap." To make this case, the most extreme (rather than typical) price differentials are cited. Thus, consumers are led to believe that such differentials are commonplace. Even your knowledge and your motives as a physician are questioned.

Understandably, these views have created myths. We think it's time to examine them in the light of all the facts and ramifications.

*MYTH: There are no differences in quality and performance between brand-name products and their generic counterparts. The corollary is that there are no differences among products made by high-technology, quality-conscious, research-based companies and those made by commodity-type suppliers.*

**FACT: The Food and Drug Administration does a good job in monitoring a generally excellent drug supply. Still, it has nowhere near the resources to guarantee the quality and bioavailability of all marketed products at any given time. Just a few months ago, for example, it noted that batches of tetracycline HCl capsules which met official monograph requirements were not bioequivalent to a reference product. As you know, there is substantial literature on this subject affecting many drugs, including such antibiotics as tetracycline and erythromycin. The record on drug recalls and court actions affirms strongly that there are differences among pharmaceutical companies and their products. Research-intensive companies have far better records than those that do no research and may practice minimum quality assurance.**

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*MYTH: Industry favors only "expensive" brand names and denigrates all generics.*

**FACT: PMA companies make 90 to 95 percent of the drug supply, including, therefore, most of the generics. Drug nomenclature is not the important point; it's the competence of the manufacturer and the integrity of the product that count.**

# Matters.

*MYTH: Generic options almost always exist.*

**FACT: About 55 percent of prescription drug expenditure is for single-source drugs. This means, of course, that for only 45 percent of such expenditure, is a generic prescribing option available.**

*MYTH: Generic prescriptions are filled with inexpensive generics, thus saving consumers large sums of money.*

**FACT: Market data show that you invariably prescribe—and pharmacists dispense—both brand and generically labeled products from known and trusted sources, in the best interest of patients. In most cases the patient receives a proven brand product. Savings from voluntary or mandated generic prescribing are grossly exaggerated.**

*MYTH: Drugs account for a major portion of the rise in health care costs.*

**FACT: Drugs represent a very small part of such costs. The amount of the health care dollar spent for prescription drugs was about 12 cents in 1967; today it is about 8 cents. And you as a physician are most conscious of how drug therapy can cut hospitalization, avert surgery, reduce office visits and keep patients on the job.**

*MYTH: Government intrusions into the marketplace will save tax money.*

**FACT: Government schemes always cost the taxpayer something, and the costs often exceed the benefits. Certainly, any federal "help," such as lists of wholesale drug prices sent to all physicians and pharmacists, will be no exception. Just think of the expense of keeping them current! Moreover, wholesale prices are poor guides to actual transaction prices and even worse guides to retail prices.**

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After the myths about price and equivalency have been shattered, one fact stands out more clearly than ever: *The maker does matter.* As always, your best guide to drug therapy for your patients is to select products—both brands and generics—from manufacturers with credentials and performance records you have come to respect.

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agency that carries the public sector responsibility for child maltreatment. It arose from the Connecticut Department of Social Services (DSS—formerly the "Welfare Department") and achieved distinct departmental status in 1969. In 1974, Protective Services' responsibility was transferred to DCYS. However, an administrative aberration was created in that much of the federal funding (Title IVB) for DCYS services continued to be distributed through DSS. The DCYS budget contains minimal discretionary funds for grants to community agencies for program development. However, DCYS may request funds from DSS for distribution to community programs. The primary source of these funds is the federal Title XX allocation, which highlights "safeguarding children" as a major priority. The process for acquiring Title XX funds, however, is difficult. Categorical "requests for proposal" are not distributed, the recommendations of regional Title XX advisory boards are unevenly recognized and, if funded, the community must provide a 25 percent local cash match before a project can begin. Despite the current impediments in the distribution of Title XX funds, continual energy should be placed in the refinement of this process, for it is presently the single largest potential source of continuing support for child protection program development in the private sector.

Analogous to the negative impact that the establishment of NCCAN has had on funding from other federal sources, the establishment of a distinct DCYS in Connecticut has led the Connecticut Department of Mental Health to abdicate its responsibilities for the prevention of child maltreatment. Child abuse and neglect is to a great extent an adult mental health problem with most successful interventions aimed at parental support. However, funding for services to parents of maltreated children is not shared by the state's mental health agency.

A recent state source of support for community program development has been the Connecticut Justice Commission (CJC). Recognizing that child maltreatment is intimately related to violent behavior in youth and adults, the CJC has sponsored seven community child protection programs with federal funds from LEAA, an administration of the U.S. Department of Justice.

*Municipal Sources*—In a number of communities in Connecticut, municipal Comprehensive Employment and Training Act (CETA) administrations with funds from the U.S. Department of Labor have provided manpower for child protection programs, particularly Parent Aide Projects. CETA funding is relatively easy to acquire but CETA projects are limited to one year and long-term unemployment is a requirement for CETA employment eligibility. This non-categorical resource has been invaluable as a "starter" for nonprofessional programs.

*Private Sector Sources*—Organizations such as the United Way, the Junior League and private foundations may be helpful for "one-time" expenditures or for the provision of matching funds. It is unlikely that these resources would provide ongoing major funding of community child protection programs.

It is clear that revenue generated from clients will never play a significant role in financing community child protection programs. It is ironic that the majority of community programs in Connecticut are presently dependent on funds emanating from the Departments of Justice and Labor and not from HEW. However, for long-term program maintenance, the Connecticut DCYS must broadly expand its commitment to contract for preventive services with agencies in the private sector. The major funding sources will be Title XX and contributions from the general DCYS budget, the latter requiring state legislative action.

### In-Kind Manpower

While funding is necessary for the staff positions in child protection programs, the multidisciplinary nature of the problem calls for the part-time input of a variety of professionals from the community. Child Protection Teams (CPTs), for example, regularly require the expertise of physicians, social workers, attorneys, police, school personnel, Public Health Nurses, etc. In most CPTs, the time is donated "in-kind" by the agencies for whom the professionals work. These "in-kind" donations may serve as local matches for some state or federal grants. In most instances, the necessity for contributed time dictates that CPT members not be in a private professional practice. Therefore, Legal Aid Societies are the best sources for attorneys, hospital-employed physicians are the most likely to participate, etc. It has been our experience in Waterbury that "in-kind" professionals have not only been easily recruited but that some who have not been recruited have expressed considerable resentment.

### Territoriality

Territorial behavior on the part of human service professionals is a major obstacle to the development of effective child protection programs. Polarization comes in all varieties: public sector vs. private sector, hospital personnel vs. non-hospital personnel, social workers vs. physicians, etc. The multidisciplinary, multi-agency nature of responses to child abuse and neglect dictates that a respectful, trusting and egalitarian team process must develop. In many communities, a schism exists, particularly between Protective Services workers and hospital personnel, each considering the other naive, incompetent, obnoxious, etc. The families, of course, are the losers in these professional cold wars. The CPT itself serves as the most effective integrator and harmonizer for these rivalries. In the CPT, over time, professionals from different settings get to know one another personally and come to listen well, trust and recognize each other's unique skills. Once everyone realizes that a unidisciplinary approach (regardless of the discipline) is inferior to a multidisciplinary process, territoriality becomes a non-issue. At that point, child maltreatment "belongs" to the community.

### Confidentiality

While information sharing is crucial for enlightened decision-making in child maltreatment cases, a family's right to privacy and confidentiality of records are realities which must be respected. The ethical and legal issues are real and difficult but are, unfortunately, occasionally "used" in the defense of outmoded unidisciplinary approaches. The ethical issue is approached (by the authors) by viewing a child's right to wellbeing as superseding a parent's right to privacy. The legal aspects of confidentiality have been dealt with by the CPT in compliance with PL-75-524, Section 20, the Connecticut statute governing disclosure of confidential information. This statute states that "consent of a person shall not be required for the disclosure or transmission of communication of the person . . . when the communication or records are disclosed to individuals or agencies engaged in medical, psychological or psychiatric diagnosis, treatment or education of the person and the Commissioner determines that the disclosure is needed to accomplish the objectives of diagnosis, treatment or education."

The following are Protective Services' policies for information disclosure to the CPT: (1) the Protective Services worker shall inform the client that the CPT will review his case, explaining the nature of the CPT and the purpose of the CPT meeting; (2) if possible, the Protective Services worker shall obtain the client's written consent for DCYS to discuss his case with the CPT; (3) if a client does not give his written consent, the DCYS Regional Director will sign a statement stating that he determines that the disclosure by DCYS to the CPT of the communications and records of a client is needed to accomplish the objectives of medical, psychological or psychiatric diagnosis, treatment or education; (4) statement of consent from a client or statement from the Regional Director shall be kept in the case file; (5) any written records given to the CPT must be stamped "confidential" and must be returned to DCYS following the meeting.

## Areas for Program Development

Hospitals, through their policies and programs, and individual hospital personnel, through activities within a community, can potentially improve the quality of family functioning and reduce the incidence of child abuse and neglect through a variety of approaches. These approaches can be grouped into four major categories: primary prevention, secondary prevention, education and advocacy.

### Primary Prevention

The ultimate goal of program development in child abuse and neglect is primary prevention, i.e., the enhancement of family functioning to the extent that maltreatment does not occur. The health system occupies a unique position for this purpose since it is the only setting in our society through which children and families pass en masse prior to entry into the educational system. Given the importance of early parent-infant attachment,[1] the morbidity and mortality of abuse and neglect in infants and toddlers,[2] and the predominant impact of the first three years of life on child development,[3] an active, expanded role for the health setting in the enhancement of family development is a logical imperative. Though some "experts" argue that maltreatment is largely a consequence of socio-cultural factors,[4] leading to poverty, crowding, malnutrition, hopelessness, etc., child abuse and neglect is not by any means an exclusively indigent phenomenon.[5] The elimination of poverty would indeed matter, but early individualized support mechanisms fostering positive family development are crucial as well. Summarized below are a variety of primary prevention approaches which may be taken by hospitals.

*Enhancement of Parent-Infant Attachment (Bonding)*—Many investigators, but particularly Klaus and Kennell,[1] have demonstrated that early and extended contact between parents and their newborns has a persisting positive effect on the quality of parent-infant attachment. Vietze[6] has recently reported that, in a randomly-selected population, there was strikingly less child abuse and neglect among families who used "rooming-in" as compared with families whose infants stayed in the "well baby nursery." Klaus and Kennell have recommended a number of perinatal routines which will serve to enhance parent-infant attachment:[1] (1) An individualized assessment should be made of each mother's needs and desires relating to the birth experience and the new infant; (2) Thorough prenatal preparation should be provided including information regarding labor and delivery and newborns, preparation for labor, e.g., LaMaze classes and tours of the obstetrical and newborn facilities; (3) A single individual should be with the mother throughout labor and delivery. This is ideally her husband but many individuals can fulfill this role; (4) Eye medication (silver nitrate) should be delayed until approximately one hour of age so that the parents and infant can experience reciprocal eye-to-eye contact while the infant is in the "quiet alert" stage; (5) If the mother and newborn are well, the mother, father and newborn should be allowed to interact alone for 30 to 45 minutes before the administration of silver nitrate drops and the onset of the infant's first nap. It is obvious that systemic anesthesia and and analgesia can interfere with this initial attachment period; (6) Rooming-in should be available and encouraged for all well mothers with well newborns. The mother should be given complete responsibility for the care of her baby, with the nursery staff immediately available as consultants; (7) Family visiting should be unlimited and strongly encouraged. Mother, father and siblings all benefit from the mutual support and intimacy of this special time.

The American College of Obstetrics and Gynecology has recently expressed great concern about the potential hazards of home delivery.[7] The development of quality family-centered obstetrics in hospitals would be the single greatest deterrent to home deliveries. Indeed, in countries where family-centered hospital birthing experiences are the routine, there is minimal consumer interest in home delivery.[8] Klaus[9] has predicted that the near future in the United States will bring hospital "birthing centers" and the abolition of well newborn nurseries as the rule rather than the exception.

*Early Identification of Families in Need of Services*—The early identification of families who may be particularly vulnerable to manifest harmful child-rearing behavior is a critical necessity though the subject of considerable controversy. Four major criticisms of early screening programs have been articulated: (1) the state of knowledge of the antecedents of maltreatment is inadequate to develop a screening instrument;[10] (2) screening may lead to labeling, false labeling and self-fulfilling prophesies of child maltreatment;[11] (3) even if vulnerable families were identifiable, adequate resources would not be available for intervention;[12] and (4) screening may highlight the weaknesses rather than the strengths in families.[13]

It is our view that the designers of early intervention programs should pay close attention to these pitfalls, but that with current knowledge and resources, early identification programs can have a positive outcome in terms of primary prevention of maltreatment. Gray, et al.,[14] have conducted a perinatal assessment study which has demonstrated the ability to identify high-risk families and further, that intervention in these families prevented maltreatment when compared with "high risk" non-intervention families." Particularly predictive were labor and delivery-room observations which focused on : how does the mother look? what does the mother say? and what does the mother do? With or without a protocol, observant, focused, objective medical and nursing staff should assess the strengths and weaknesses demonstrated by parents and not be reluctant to identify those families that are in need of extra supportive services. Kempe contends that, rather than being a preoccupation with weaknesses and an exercise in labeling, early identification and service provision is the practice of "preventive pediatrics at the highest level."[15]

What are the "services" for a family in need of services and are they, in fact, unavailable? All of the following could be made available to vulnerable families with the present resources in Connecticut: (1) physician-nurse-social worker teams in prenatal and pediatric settings to provide continuous, frequent and personalized support to families; (2) Parent Aides for primary prevention; (3) Public Health Nurses and Visiting Nurse Association personnel; (4) day care for siblings; (5) Homemakers; (6) mental health and family service agencies; (7) family planning services; (8) drug and alcohol treatment programs; (9) "battered spouse" shelters; (10) Parents Anonymous.

While some services, e.g., crisis nurseries, are not yet developed in Connecticut, and many of the above services need to be expanded, there is by no means a vacuum of support services for these families.

*Parent Education*—Most hospitals have some form of prenatal classes which generally focus on "having the baby" rather than on "being a parent." Often new parents know very little about infant health and almost nothing about child development and behavior. Considering the role of inappropriate expectations and interpretations of infant development and behavior in the etiology of maltreatment,[16] education for parents needs to be broadly expanded. The hospital, with a relatively captured population, should, on an individual and group basis, develop high quality parent education programs in both the obstetrical and pediatric settings. There should be flexibility for educational level and ethnic content, and child development and behavior should be emphasized.

*The "Health Visitor" Concept*—The most recent and dramatic recommendation for program development for primary prevention has come from Dr. Kempe.[17] Taking a cue from European programs where registered nurses serve as routine health visitors, a study was conducted in Aberdeen, Scotland,[15] wherein every child born in that city was visited at home by a registered nurse for a two-year period. The results revealed that these health visitors could very accurately identify the antecedents of maltreatment in the home setting. Subsequently, a number of projects in the United States utilizing lay health visitors with professional supervisors has been undertaken. For the past year all parents of infants born in Colorado General Hospital have been offered the services of trained lay health visitors. Approximately 65 percent of the families have accepted these services. To date, no child born during this time period at Colorado General Hospital has been hospitalized in Colorado for maltreatment. Previous hospital experience would predict that there would already have been at least five hospitalizations from this group (personal communication, C. Henry Kempe). Further information regarding the efficacy of lay health visitors will be forthcoming over the next few years and public policy will ultimately determine whether mandatory health visiting programs will develop. The legal precedent for mandatory programmatic child advocacy exists in the enforcement of educational experiences for children in the United States. Whether this philosophy will extend to the mental and physical well-being of infants and young children remains to be seen. In the meantime, hospitals and their personnel should fully utilize the services of Public Health and Visiting Nurse programs. It has been our experience that nurses with skills in maternal-child health have been the most warmly received of all health and mental health professionals who visit households.

**Secondary Prevention**

Secondary prevention measures include those activities which occur in response to the identification of maltreatment in a given family. Considering the magnitude and complexity of the problem, effective hospital responses will not occur unless systems change, embodied in enlightened policy and program development, takes place. Without a thoughtful, organized approach to these cases, regardless of the skills of individual professionals, some children will "fall through the cracks" and remain at-risk for further maltreatment.

*The Development of Hospital Guidelines for the Management of Child Abuse and Neglect*—A model to assist in the development of hospital policies has recently been published.[18] Hospital protocols should include at least the following: (1) Protective Services reporting mechanism—oral and written; (2) the use of the 96-hour medical "hold;" (3) emergency room management protocol; (4) inpatient management protocol; (5) CPT referral mechanism; (6) Department of Social Work responsibilities; (7) sexual assault cases protocol.

*Child Protection Teams*—The justification for multidisciplinary case management and the history of the Waterbury Regional CPT have been described.[19] At present there are eleven multidisciplinary CPTs in Connecticut. These are either directed by, or are in conjunction with, personnel from the following hospitals: Bridgeport, Dempsey, Danbury, Griffin, Manchester, Middlesex, Yale-New Haven, Mount Sinai, St. Mary's andWaterbury. The development of multidisciplinary CPTs is not only a necessity for case management but will serve as a catalyst to the implementation of a variety of other child-protection related activities.

*Parent Aide Programs*—The lay therapy concept and the Waterbury Parent Aide Project have been described.[19] At present there are six such projects in Connecticut (Bridgeport, Hartford, Middletown, Derby, New Haven and Waterbury). Of these, the Hartford and Waterbury projects are based in medical settings. While it is by no means necessary that these programs be in a medical setting, hospitals can certainly take the initiative in program development, either by direct implementation or by advocacy for a fellow community agency.

*Parents Anonymous*—In 1971, the first attempts at application of the self-help model were begun as "Mothers Anonymous" in California. Since that time there has been a remarkable proliferation of this highly successful approach, now known as Parents Anonymous (PA). At present there are approximately 800 PA chapters in the United States and abroad. In Connecticut, there are 30 active chapters in 26 communities. The Connecticut Child Abuse Care-Line serves as a centralized referral mechanism for all Connecticut PA chapters. This self-help approach (1) allows parents to share difficult feelings with other parents in a non-threatening, non-judgmental, supportive setting, (2) provides 24-hour "lifelines" and combats social isolation for parents and (3) allows parents to develop more appropriate expectations of their children's development and behavior. PA has proven to be the most effective of all interventions for child maltreatment with recidivism rates even lower than Parent Aide clients.[20]

Hospitals can support PA in a variety of ways. A hospital itself may choose to sponsor a PA chapter with support for publicity, provision of meeting space and provision of a professional sponsor for a group. This is frequently done by hospital auxiliaries as was the case in Connecticut at Manchester Memorial and Yale-New Haven Hospitals. Hospitals can provide "release time" for a few hours weekly for a professional to be a PA sponsor in the community. Hospitals can help community PA chapters with publicity by displaying PA posters in strategic areas such as emergency rooms, pediatric clinics and social service offices. Finally, hospital personnel working with parents should make appropriate referrals to local PA chapters.

**Education**

The approaches to the prevention, diagnosis and management of child abuse and neglect are relatively new to many health professionals. The majority of the primary and secondary prevention strategies have been developed in the past decade and are at only an introductory stage in many communities. Therefore, the development of inservice education programs for personnel, particularly physicians, nurses and social workers, is a necessity. Contents should include general information about maltreatment, an understanding of the Child Protection law, and orientation to specific hospital protocols for management.

Teaching hospitals should include child abuse and neglect in curriculum development for residents, medical students and nursing students. Those hospital personnel with experience and knowledge in the field should participate in community-wide inservice education, particularly in the context of multidisciplinary panels. Finally, hospital personnel can contribute to general public awareness by addressing lay audiences via PTA meetings, television, radio, etc.

### Advocacy

Physicians should not underestimate their potential influence, especially in the public sector, as advocates for children and families. Public policy decisions in areas such as social services, health and mental health services, housing and education, can have an enormous impact on family functioning. A physician, well armed with information, can influence the policy on behalf of families in a number of settings, including school boards, regional health, mental health and social services advisory boards, state legislative hearings and local municipal executive bodies.

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*(This is the third of a series of three articles.)*

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# Sudden and Suspicious Deaths: Changes in Connecticut, 1969-1979

ELLIOT M. GROSS, M.D.

**ABSTRACT—Legislation passed in 1969 created a commission on medicolegal investigations and a medical examiner's office, the first major alterations in death investigation in Connecticut since 1883.**

**Location of a central facility on the University of Connecticut Health Center campus; an increase in medicolegal autopsies; availability of toxicological confirmation in suspected fatal poisonings; and collection of mortality data for use by other health and governmental organizations are among changes instituted in the decade since the Medicolegal Investigations Act became law.**

## Introduction

June 26, 1979 denotes a decade since the Medicolegal Investigations Act became law. Patterned after a model postmortem examinations act, it instituted Connecticut's first major change in death investigation since 1883. The 1969 legislation created a medical examiner's office directed by a forensic pathologist under supervision of an independent administrative commission.[1]

Borough coroners of New York City, lacking both legal and medical training and occasionally employing a corrupt physician, were replaced in 1918 by the first office for death investigation to be directed "by a doctor required to be a skilled microscopist." This office of chief medical examiner, open every day, was obligated to maintain properly indexed records, open to public inspection, on every death reported. These included all accidental, homicidal and suicidal deaths and those of persons dying suddenly, medically unattended, or in prison; or whose bodies were to be cremated. The medical examiner was responsible for responding to the scene of a reported death and to perform an autopsy, if, in his opinion, it were necessary. The records of a death resulting from a criminal act had to be forwarded to the district attorney.

Statutory changes similar to those in New York were first instituted statewide in Maryland in 1939 and by 1969, in sixteen other states. Connecticut's legislature, retained county offices of coroner, establishing a dual system. [Similar provisions existed as of January 31, 1977 in seven other states.[2]]

Criticisms of lay systems include reluctance to perform an autopsy except in an overt homicide and inadequate investigation of deaths in public institutions.[3] Thus an asphyxial death by strangulation may go unrecognized in the absence of external trauma to the neck.

Benefits of a medical examiner system in addition to detection of homicides, include recognition and documentation of traumatic and chemically induced causes of injury and death. These provide data for research and scientific purposes, ultimately for the good of the public health and safety.

The Government Reorganization Act of 1977 placed the Commission on Medicolegal Investigations in a Department of Health Services, effective January 1, 1979. This article briefly reviews changes in death investigation since appointment of the first commission.

## Legislative History in Connecticut

While responsibility for death investigation is derived from duties of the medieval coroner, the title did not appear in Connecticut's initial statutes. The Code of 1650 called for a magistrate or constable to form a jury of six or twelve to determine the cause and manner of an "untimely death" and to return a verdict to a magistrate. Similar provisions appeared in the "Acts and Laws of the Colony of Connecticut in New England in 1702" and the "Acts and Laws of the State of Connecticut in America in 1776." Subsequent statutes required that a verdict be returned to a justice of the peace who forwarded it to superior court.

Mention of a physician first appeared in 1853. The law then specified that a "competent person or surgeon" be employed by a grand juror or a prosecutor to make a post mortem examination upon the body of a person "found dead under circumstances justifying suspicion" of death from violence or poison for purposes of "obtaining the proper evidence in relation to the death . . . and the cause of death."

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The magisterial inquiry conducted before a jury of six was named a coroner's inquest by 1875 although an official by title of coroner did not exist. There were no provisions for medical testimony or findings until eight years later.

The Coroner's Act of 1883 stipulated that superior court justices upon recommendation of the state's attorney, appoint as county coroner, an attorney familiar with criminal justice and medical jurisprudence. Serving a three-year term, he, in turn, appointed a physician in each town to serve, at his pleasure, as medical examiner. An autopsy was to be performed by a medical examiner, surgeon or other physician in a death from a criminal act, omission or carelessness of another. The coroner's inquest was retained. Subordination of medical examiner to prosecutor and absence of an autopsy as a prerogative were criticized: "time will undoubtedly show the law's defects and, if it has any, its advantages."[4]

Statutes concerning death investigation remained essentially unchanged until 1949 when a toxicology laboratory was initiated in the State Department of Health and certification by the American Board of Pathology was required of pathologists performing medicolegal autopsies. Bills to abolish the office of coroner and establish a medical examiner's office, or a position of chief medicolegal officer in the Department of Health, failed to be reported out of legislative committee.

No further legislation was enacted until 1967 when the coroner's jury was abolished, and 1969, when the Commission on Medicolegal Investigations was created. At the same time provisions for presence of counsel at hearings and submission of coroner's reports of findings in motor vehicle accidents to the State Motor Vehicle Commissioner were altered. Statutes requiring testimony of a pathologist and other persons that constituted an inquest without a jury were, however, repealed.

### Commission on Medicolegal Investigations

The commission is composed of nine members, appointed by the Governor, serving without pay and including professors of pathology and of law from the University of Connecticut and Yale and representatives of the Connecticut Bar Association, Connecticut Medical Society, and the public. They serve six-year terms, and the State Health Commissioner serves ex officio.

Physicians on the commission have included Donald R. Hazen and Vincent D. O'Neil, Connecticut State Medical Society; Irwin H. Lepow and Peter A. Ward, Professors of Pathology, University of Connecticut; Robert V.P. Hutter, Lewis Thomas, Levin L. Waters, and S. Evans Downing, Professors of Pathology, Yale University; and Franklin M. Foote and Douglas S. Lloyd, ex officio.

The commission meets quarterly and has responsibility for appointment of the chief medical examiner and designation of his term of office and salary; review of budgetary requests; and promulgation of regulations. Appointment of assistant medical examiners are subject to its approval.

At its initial meeting on November 7, 1969, the commission designated the University of Connecticut Health Center as the site for the Office of the Medical Examiner. (The statutes called for the chief medical examiner's office to be located at a medical school in the state.) During its initial year the commission consulted with the late Milton Helpern and Joseph Spelman, then chief medical examiners of New York City and Philadelphia.

Regulations adopted in 1974 provided for telephone reporting by hospitals of deaths subject to investigation and for initiation of a report form by a physician last in attendance. This form, a copy of which remains in the patient's hospital record, serves to provide information without the necessity of a medical examiner reviewing a copy of the entire record. Where an autopsy is to be conducted at the Office of the Medical Examiner, the form is transmitted prior to the examination. Knowledge of roentgenographic documentation of rib fractures on admission of an elderly motor vehicle driver who expires several hours later after an attempt at cardiopulmonary resuscitation; or of administration of lidocaine, a drug of abuse, to correct an arythmia in a heroin addict pronounced dead 45 minutes after admission are critical to evaluation of autopsy findings and certification of cause of death, for registration of vital statistics and for legal purposes.

Other regulations effecting change pertained to release of records and unclaimed bodies. Records are furnished to authorized representatives of next of kin and others with a legitimate interest. Copies of reports of autopsies performed at the Office of the Medical Examiner are forwarded, upon request, to physicians who have treated patients. Those performed at community hospitals may also be obtained from pathologists conducting examinations.

Unidentified and unclaimed bodies are retained at the Office of the Medical Examiner or a hospital mortuary to insure a search for identification and next of kin with subsequent release to a funeral home designated by them. Previously funeral homes were designated, sometimes on a political basis, as "town morgues" for such bodies.

### Appointment and Duties of Medical Examiners

Assistant medical examiners perform preliminary examinations at the scenes of reportable deaths and at hospitals; authorize autopsies; certify deaths and approve cremations. Where a physician's patient dies at home, the medical examiner may be called by police to pronounce death. Frequently, however, this is the responsibility of the attending physician who may have seen him within a short period prior to death; or his designate.[5] The medical examiner should be called if the responsible physician has any questions concerning the certification of the cause of death as due to natural disease.

Appointment of medical examiners is made following application to the chief medical examiner and recommendation by physicians in the community in which the physician is to serve. Periodic orientation meetings are held and an annual program is conducted in Farmington. Currently 107 physicians, representing twelve medical specialties serve as assistant medical examiners in Connecticut's eight counties.

### Office of the Medical Examiner

The Office of the Medical Examiner (initially Office of Medicolegal Investigations) was established effective July 1, 1970. A trailer at Hartford's McCook Hospital and its autopsy room were used from May 1971 to July 1974. Since then a building on the University of Connecticut Health Center campus, renovated for $324,000, has provided 6,500 square feet for administrative offices; identification room, autopsy area and mortuary; and toxicology and histology laboratories. The 1977 legislature authorized a bond act appropriation of $200,000 for planning of a permanent facility, similar to those constructed, in the past twenty years, for offices of chief medical examiner in New York City, Maryland, Delaware, Rhode Island and other states.

During fiscal year 77-78, $890,372 was expended by the Office of the Medical Examiner of which $298,144 was for services of twenty-seven personnel including two pathologists. Staff was responsible for transportation to Farmington of 176 cases; assistance at 431 autopsies; and toxicological analyses in 459 cases. $536,740 was disbursed for 6,955 investigations and examinations by medical examiners and 1,031 autopsies performed by 93 pathologists at thirty-two community hospitals.

A clerk is present at all times and police, hospitals, and physicians report, by telephone, all deaths to be investigated by assistant medical examiners. Discussions concerning necessity for autopsy are carried out by assistant medical examiners with pathologists at the Office of the Medical Examiner. Decision for an autopsy is based on the judgment of the medical examiner in charge, taking into consideration circumstances of a death as well as the body's external appearance:

A 52-year-old white male, on reserpine for hypertension, was found dead in Somers prison. Two years previously he had sustained a mild paresis of the left face and upper and lower extremities which had cleared within 48 hours. The necessity for an autopsy in a case, initially reported as a death due to a myocardial infarct, was questioned.

Autopsy revealed severe occlusive coronary arteriosclerosis, but also a right subdural hematoma ("occurring incidentally when he fell following the cardiac arrest"). Examination a day later of preserved subdural, right temporal and frontal lobes, and sylvian fissure disclosed, however, a ruptured, partially calcified 4.5 cm. saccular aneurysm of the right middle cerebral artery. Adherent to the blood clot as well as the underlying cerebral cortex, the aneurysm, which had leaked previously, had ruptured into the subdural space causing death.

In view of the apparent cardiac cause of death both before and following autopsy and of the initial interpretation of an incidental traumatic etiology for the subdural hematoma, the autopsy, and its documentation were performed in the public interest. The inmate's incarceration resulted from conviction for his participation in the robbery and murder of six individuals.

During the first eight fiscal years, the number of deaths reported rose from 6,291 to 8,823 and the number of autopsies authorized from 876 to 1,383. Of the latter 1977-78 figure, 431 were conducted at the Office of the Medical Examiner. These included 96 cases of homicide (75% of the 128 which occurred in the state.)

Deaths requiring medicolegal investigation comprise 25-30% of those occurring in a jurisdiction and depending on whether it is urban or rural, 20-25% require autopsies. The increase in autopsies in Connecticut has been the result of authorization in instances in which they were not performed prior to 1970. These include driver fatalities, deaths from drug abuse and infants dying as a result of the sudden infant death syndrome: autopsies of infants dying under one year of age rose from 65% of deaths in 1970 to 99% in 1978. This policy has served to detect homicides:

A three-week-old white female was brought to a hospital by her father who noted her unresponsive in her crib, 30 minutes after last being seen alive. Delivery had been normal and she had been discharged three days later with a weight of 5 lbs., 10 oz. Cardiopulmonary resuscitation restored a cardiac rhythm and, maintained on a respirator, she was transferred two hours later to a second hospital where x-ray of long bones showed a doubtful fracture of left radius. She died 48 hours later without external injury and with an apparently normal chest x-ray.

Autopsy, disclosed multiple healing rib fractures, cerebral contusions, subdural hematoma, and a hematoma of the right adrenal gland. The fractures were noted on re-examination of x-rays from each of the two hospitals to which she had been brought unconscious.

Autopsy permission had not been solicited from the parents by house staff who had been in touch with the Office of the Medical Examiner prior to death. The father admitted shaking and squeezing the child and pled guilty to second degree manslaughter in this apparent "crib death."

While cause of death is frequently evident at autopsy, microscopic and/or chemical examination may be necessary before a conclusion can be reached. A delay of three to four months in reports of analyses on biological tissues and fluids submitted from autopsies to the Health Department's toxicology laboratory, was noted in 1953.[6] This extended to as much as two years by 1970, as analyses of drugs and other evidence needed by courts took precedence.

In accordance with legislation, a toxicology laboratory was established in the Farmington facility in 1975. In the twelve months ending June 30, 1978, 459 cases were analyzed representing a 62% increase over the 286 of the previous year. These consisted of analyses of tissues and biologic fluids removed from 375 autopsies at the Office of the Medical Examiner (82%) and 84 at community hospitals (18%).

Centralized reporting of deaths and the ability to analyze post-mortem tissue is important in recognizing a danger to the public and preventing further fatalities due to toxic substances. Fluorocarbons and other drugs were identified in three individuals (ages 16, 16 and 20) who inhaled aerosol propellants within a six-week period. The potential fatal nature of this form of substance had been recognized and well publicized in 1970. The aerosol containers in each of the Connecticut cases clearly designated the hazards of inhaling concentrated amounts of their contents. Because only two deaths had occurred between July 1, 1970 and September 7, 1978, the public was reminded of the aerosol dangers.[7]

Records maintained in Farmington contain original medical examiner's reports, autopsy protocols and toxicological findings in each of 8,000 deaths reported annually since 1970. These provide mortality data, not elsewhere available, and are regularly used by the Connecticut Cancer Registry for follow up of patients reported to it; Connecticut Department of Motor Vehicles for studies relating to alcohol; maternal mortality committee of the Connecticut State Medical Society; and U.S. Consumer Safety Commission to identify products causing fatalities.

## Conclusion

The purpose of death investigation is frequently conceived of as identification of foul play. Homicides and suspicious deaths (those referred to State's Attorneys for further investigation) however, accounted for only 135 (1.6%) of 8,602 deaths reported in 1978.

In addition to meeting criminal justice requirements, Connecticut's medical examiner system, has also been concerned with public safety, public health, and medical education.

Investigation of Connecticut's first commercial aircraft disaster in 1971 resulted in recognition that injuries had incapacitated the lone flight attendant. This prevented her from opening a cabin door for passengers all of whom died of smoke inhalation and carbon monoxide. As a result, the National Transportation Safety Board made thirteen safety recommendations including changing the door handle's configuration and location of directions to permit a passenger to open the door in the event passage were impeded.[8]

Institution of a uniform policy of investigating deaths due to sudden infant death syndrome, in addition to identifying homicides (infant deaths which would not be detected were "foul play" to be the sole criterion for autopsy) has been instrumental in establishment of a federally funded statewide management program. Through this program, jointly conducted with the State Health Department, parents are promptly informed of the reasons for an autopsy and are notified through a letter, within 48 hours, of their results from the medical examiner investigating the death. Provisions are made for visits by a public health nurse and death certificates no longer erroneously list suffocation as a cause of death.

The mutual benefits of relating a medicolegal office to a medical school have been exercised in regards to education as well as death investigation.[9] University of Connecticut first-year and Yale University second year medical students receive lectures in pathology of physical and chemical agents.

First year students at the Health Center witness autopsies at the Office of the Medical Examiner as part of their introduction to pathobiology. During the current academic year, seven third and fourth year University of Connecticut medical students will spend one month electives in forensic pathology, learning the effects of trauma, as well as of drugs and poisons, on the human body. Residents in anatomic pathology both from Hartford and other hospitals have spent elective periods at the Medical Examiner's Office.

These are but three effects of implementing, over the past decade, the 1969 legislation which changed the investigation of sudden and suspicious deaths in Connecticut.

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# Status Report on Second Surgical Opinions

*The following is a report prepared by the Council on Medical Service of the AMA and accepted by the AMA House of Delegates at its November-December Convention in 1978.*

At the AMA's 1976 Annual and Clinical Conventions, and the 1977 Annual Convention, the Council on Medical Service reported to the House of Delegates on the status of third party payor programs offering benefits for a "second opinion" on elective surgical procedures. The reports identified a number of questions which required longterm study concerning the impact of "second opinion" programs on the health status of the population involved, and urged that there be no further proliferation of such programs until the experience of those then operating, and their impact on quality and costs of care, could be better evaluated. A number of issues of immediate concern to medicine were discussed, including possible restrictions in choice of physician to render the second opinion, whether such second opinions were to be voluntary or mandatory, the need for complete exchange of patient information between attending and "second opinion" physicians, possible adverse effects of such programs on the physician-patient relationship, and questions of increased exposure to legal liability by the physicians involved. Also at the 1977 Annual Convention, the House adopted Resolution 77, which read as follows:

RESOLVED, That the House of Delegates of the American Medical Association adopt a policy statement on mandatory consultation as follows:

> "Recognizing that the advisability of surgery or other specific therapy can be a matter of opinion, the House of Delegates of the American Medical Association (1) reaffirms the right of a patient or a physician to seek consultation freely with any consultant of his/her choice; (2) opposes the concept of mandatory consultation when required by a third party payor; (3) supports the concept that when consultation is required by a third party payor, the consultation should be at no cost to the patient; (4) opposes the concept of closed panels of consultants, and (5) supports the concept that if consultation is required by a third party payor, the patient should be allowed to choose a physician of his/her choice."

At the 1978 Annual Convention the House of Delegates reaffirmed Resolution 77, and also endorsed Recommendation 27 of the National Commission on Cost of Medical Care concerning such programs. Commission Recommendation 27 read as follows;

> "Third-party payers, working with providers, should undertake conscientious evaluation of the methodologies and the results of current experimentation with coverage of second opinions prior to elective surgery. The long-term results and general adaptability of such programs should be evaluated in terms of medical care quality, cost effectiveness, the cost and quality of alternative care provided in place of surgery, and the long-range medical implications for the patients who did not have surgery."

The purpose of the present report is to apprise the House of significant developments in this area since that time, and of Council and other Association activities designed to implement established policy concerning these programs.

### Government Activities

Early in 1978, in the wake of Congressional hearings on "Unnecessary Surgery", the Secretary of the Department of Health, Education and Welfare announced the Department's intention to promote the seeking of second surgical opinions by the public, particularly Medicare and Medicaid beneficiaries, and to identify, through HEW regional offices, local organizations such as PSROs, Medicare carriers or medical societies who would develop and maintain lists of physicians willing to provide such second opinions. (Such second opinions are already paid for by Medicare, subject to the normal deductible and co-insurance provisions, even though not specifically identified as such; HEW's stated intention was to encourage greater use of this benefit.) State Medicaid agencies are also being encouraged to pay for such consultations, and to refer recipients to the appropriate source of information on physicians willing to provide the second opinion.

At HEW's invitation, staff of the Association met with personnel of the Health Care Financing Administration to convey AMA policy regarding the operation of such programs. Concern was expressed at the scope of the HEW effort in view of the lack of any clear evidence to date that such second opinions would impact favorably on either quality or costs of care. In the face of HEW's announced intention to promote such programs, however, it was felt important to advise the Department of AMA views in an effort to ensure that such a benefit be voluntary for the patient and with free choice by the patient of the second opinion physician, as called for by AMA policy.

The HEW program opened formally after Labor Day with an extensive media campaign including radio and television messages and mass distribution of a brochure on the program to Medicare beneficiaries and others. A toll free telephone number has been established to provide general information and a local number to call for those interested in seeking a second opinion.

As of September, 1978, 84 medical societies, 44 insurance carriers, 30 PSROs and one state Social Security office were serving as "list holders"—sources of referral to physicians willing to render a second opinion—covering all areas of the U.S. By calling the source in his area, a patient will be given the names of two or three area physicians from which to select a consultant. It is estimated by HEW that about 55,000 physicians have agreed to participate in this program to date.

As presently operated, use of the second opinion by Medicare beneficiaries is voluntary, not mandatory, and the second opinion does not control payment for the surgery in question.

Most states are participating or are planning to participate in the project for their Medicaid patients. The only Medicaid program to date in which the second opinion is mandatory rather than voluntary is that in Massachusetts, where such an opinion is required before payment will be authorized for any of eight specific elective surgical procedures. Payment for the surgery is not conditioned on the consultant's recommendation, however.

DHEW is funding two Blue Cross/Blue Shield administered demonstration projects in New York and Michigan for second opinion programs involving 2 million Medicare beneficiaries. The Department advises that they will also fund a 4-5 year evaluation of the influence on surgery rates and quality of care exerted by the Michigan and New York demonstrations, the Massachusetts Medicaid program and the nationwide effort.

### Prudential Second Opinion Program

In July of 1978, the Prudential Insurance Company of America sent letters to some 33,000 Board certified surgeons in the United States, inviting them to participate as panelists in second surgical opinion programs to be offered to Prudential group accounts throughout the country. As certain aspects in the Prudential program appeared to be in conflict with AMA policy, and because of concerns expressed by a number of physicians about this activity, the Council's Subcommittee on Second Surgical Opinions met with Prudential's Vice President for Group Claims in the latter part of September for an indepth discussion of this program.

According to the Prudential representative, the solicitation of physicians was undertaken following two years' experience with a pilot second opinion program offered by Prudential to its home office employees in Northern New Jersey. In this program, in which the second opinion was voluntary (at the option of the beneficiary), about 20% of those for whom elective surgery was recommended did utilize a second opinion, and in 28% of these cases, the second opinion did not confirm the initial recommendation for surgery. (The Prudential representative attributed the relatively high utilization rate in this pilot program to extensive informational and promotional effort with eligible beneficiaries.)

At the time of the Committee's meeting with Prudential, about 23% of the surgeons contacted had agreed to participate on second opinion panels, but no group clients had as yet purchased this benefit.

The Committee discussed at length with Prudential two specific aspects of their program which appeared to be troublesome to many physicians:

### Restrictions on Surgical Benefit:

Two second opinion policy options are to be offered to group clients under the Prudential program. The first would provide the policy's scheduled or reasonable and customary benefit for surgery regardless of whether a second opinion was sought or whether such a second opinion confirmed or did not confirm the need for surgery. The second option, to be offered at an individually determined group premium reduction of up to 6%, would provide a lower surgical benefit if the claimant had the surgery without getting a second opinion or after receiving a non-confirming second opinion. The choice of policy option would rest with the group purchaser. The Committee stressed to the Prudential representative its belief that the financial coercion toward a second opinion resulting from this "reduced benefit" option differed only in degree, not kind, from mandating such second opinions, and that experience with second opinion to date in no way justified such an approach.

### Restriction in Choice of Second Opinion Physician

The Program Description sent by Prudential to solicited physicians indicates that Prudential will designate the physician to render a second opinion when a claimant requests the benefit. The Prudential representative indicated than an attempt would be made to provide the claimant with the names of two or three participating physicians from which he could choose, and also indicated that the program would pay for a second opinion from a non-participating physician, but only if that physician was Board-certified in surgery, and would accept the $50 fee provided by the program as payment in full for the second opinion. The inconsistency of this approach with current AMA policy supporting the right of a patient to seek consultation from a physician of his choice was similarly emphasized in the discussions with Prudential. As indicated in its previous Report J (C-76) on this subject, the Council does not believe it inappropriate for a local medical society or other group to compile lists of qualified physicians who would be willing to render second opinions. However, the patient and/or his attending physician should be completely free to select a consultant from outside that list should they wish. The Council and its Subcommittee also believe that specialty board certification is an arbitrary criterion which is not necessarily superior to any others which might be considered by any group in compiling a list of second opinion physicians, including hospital and teaching appointments, participation in continuing medical education, and similar qualifications related to experience as well as training.

Concern was also expressed to Prudential at the setting of a uniform $50 consultation fee irrespective of local variations in the cost of providing such consultations, and at the impact this could have on patients' access to a second opinion as well as his choice of consultant. The Prudential representative indicated the Company's belief that a flat fee would be "administratively more feasible" that a usual and customary or reasonable approach, but added that "appropriate adjustments" could be made if needed, and that this overall policy would be reevaluated. He further indicated that the exclusion of payment for such specific endoscopic examinations as bronchoscopy and cystoscopy in conjunction with rendering a second opinion was based on cost considerations, but that payment could be made on the basis of specific justification of need by the second opinion consultant for such examinations.

Finally, the Subcommittee emphasized to the Prudential representative the importance of marketing the second opinion benefit in a way that would not impair physician-patient relationships; and expressed its willingness to review and advise on promotional materials in this regard. The Council and its Subcommittee will continue to closely monitor implementation of the Prudential program, and recommends that individual physicians do the same, continuing to convey their concerns both to the Association and directly to Prudential as deemed appropriate.

### Status of Other Private Company Programs

The Council and its Subcommittee have met periodically with the Blue Cross and Blue Shield Association and the Health Insurance Association of America, to assess the status of other second opinion programs conducted by member plans or companies.

In December 1977, the HIAA issued a special memorandum to member companies encouraging their consideration of a second opinion program as "one of a number of cost containment methods that are consistent with quality patient care," and recommending the use of open panels of consultants with free choice by the patient, continued monitoring of the utilization and cost-effectiveness of such programs, and contact with local medical societies as the first source for names of physicians willing to participate in second opinion programs. The memorandum suggested payment for second opinions on "the basis of reasonable and customary charges" as the method most acceptable to physicians, and recommended that programs be voluntary, not mandatory. A subsequent revision deleted any recommendation as to whether programs should be voluntary or mandatory in the belief, according to HIAA representatives, that this should be left to the option of the member company and/or the policyholder.

Although exact figures are not currently available (due partially to problems of definition) it is estimated that about 100 commercial health insurance companies offer some type of second opinion benefit, primarily to group accounts. As of September 1978, about half of some 30 member companies responding to an HIAA survey indicated that they did offer a second opinion benefit. The majority of these programs at present are voluntary, although a few, like Prudential, are believed to be offering or considering a reduced surgical benefit option if a second opinion is not utilized. Figures on the utilization of this benefit in commercial plans offering it are also somewhat scanty; preliminary reports from a few larger companies, however, indicate that about 2-3% of potential beneficiaries for whom elective surgery is recommended seek a second opinion.

More recently, the Blue Cross and Blue Shield Association issued a special series of advisories to member plans on the design and administration of pilot second opinion programs. These advisories recommended that such pilot programs be voluntary, not mandatory; that surgical benefits be paid regardless of whether the second opinion was confirming or non-confirming; that the qualifications of physicians utilized as second opinion consultants be entirely at the option of the local plan and that the patient select a consultant from a list of available doctors; that identification of the attending and second opinion physician to each other be at the option of the patient; that reimbursement for consultations be based either on existing UCR allowances or on a set fee, and should constitute payment in full for the service; and that all plans offering this benefit should utilize a specified research protocol to determine the degree of program utilization and its cost-effectiveness in terms of reduced elective surgical care, as well as alternative treatment required.

According to BC/BSA representatives, at least 27 local plans currently offer a second opinion benefit, including the two previously noted HEW-funded demonstration projects by the Greater New York and Michigan plans which offer this benefit to about 2 million Medicare beneficiaries in those states. All of the plans are voluntary to date. The only Blue Shield utilization figures of significant scope as yet are those available from the Greater New York Plan, which is both the oldest Blue Shield sponsored effort—as a result of state legislation mandating the offering of such benefits—the largest (5 million eligible subscribers in August of 1976). From January 1976 to August 1977, some 1,517 persons—about 2% of the subscribers who had elective surgery—utilized a second surgical opinion. The "no-confirmation" rate on this group as a whole was 27.3%—a figure roughly comparable with data forthcoming from still older union-sponsored programs in the Greater New York City area. (Those programs show a non-confirmation rate of 33.2% for those groups for whom the benefit was voluntary, and 17.4% for those with a mandatory benefit.)

Net savings during the 18-month study period are estimated by the Greater New York Plan at about $240,000, and represent a surplus in savings of reimbursement payments over costs of program administration, promotion, and consultant and laboratory fees. About $40,000 of this amount will accrue to the Plan, and the remainder accrues to subscribers. Plan sponsors acknowledge, however, that other costs, such as those for some alternative treatment, cannot be tracked, because such treatment does not generate claims, because subsequent claims which *are* generated can not always be identified as a result of the second opinion process, or for other reasons.

Cost data from other studies are also incomplete and inconclusive as yet. For example, one of the New York City union-sponsored programs reported a 14.3% reduction in in-hospital surgical claims over a recent twelve-month period, for approximate savings of $1 million. However, data from these same programs also indicate that about 40% of those who were not confirmed for and did not have surgery performed did receive alternative medical treatment, the costs of which were not ascertained.

The Council and its Subcommittee will continue to monitor the development of second surgical opinion programs in both the public and private sectors, and to inform the House of Delegates of these activities as appropriate. As yet, the Council has seen no conclusive evidence that these programs will over the long run favorably impact on the quality, appropriateness, accessibility or costs of care, and believes that present Association policy as stated in Resolution 77 (A-77) continues to be pertinent. The Council believes that the following modification of Resolution 77, however, will both clarify its intent and make it more completely applicable to current developments in the area:

RESOLVED, That the House of Delegates of the American Medical Association adopt a policy statement on second surgical opinions consultation as follows:

> "Recognizing that the advisability of surgery or other specific therapy can be a matter of opinion, the House of Delegates of the American Medical Association (1) reaffirms the right of a patient or a physician to seek consultation freely with any consultant of his/her choice; (2) opposes the concept of mandatory consultation or the imposition of financial penalties for not obtaining such consultation by a third party payor; and (3) supports the concept that when consultation is offered by a third party payor, the consultation should be at no cost to the patient."

The Council *recommends* that the above substitute Resolution 77 be adopted by the House of Delegates.

# The National Health Planning and Resources Development Act

## Health Planning Renewal Legislation

*This is a report prepared by the Council on Medical Service of the AMA and accepted by the AMA House of Delegates at its November-December Convention in 1978.*

The 95th Congress was adjourned without renewing the health planning authority encompassed in P.L. 93-641, the National Health Planning and Resources Development Act. To enable the planning program to continue on an interim basis, Congress approved a one year extension of the program at fiscal year 78 funding levels ($107 million for Health Systems Agencies and $29.5 million for State Health Planning and Development Agencies).

Renewal of the planning authority was addressed in two bills before the 95th Congress. Both bills were concerned with: (a) health planning and resource development; (b) extension and modification of the present requirements with respect to Health Systems Agencies (HSAs), Statewide Health Coordinating Councils (SHCCs), and State Health Planning and Development Agencies (SHPDAs); (c) the National Council on Health Planning and Development; and (d) health resources development. S. 2410, which was approved by the Senate in July, 1978, contained a provision to extend the Certificate of Need (CON) program to purchasers of major medical equipment, regardless of location. The House bill, H.R. 11488, contained a modified Certificate of Need (CON) provision, which extended CON requirements to the purchase of major medical equipment in any location, if the equipment would serve inpatients of a hospital, and in addition, would have modified membership requirements on HSA governing bodies.

In September 1978, the House rejected H.R. 11488 and returned the bill to the House Rules Committee. Opposition to H.R. 11488 in the House centered on the size of the authorization for planning and construction ($1.5 billion), which included an $830 million authorization for health resources development, which was not requested by the Administration in its fiscal year 79 budget. Opponents also questioned the need for more federal regulation of the private sector. The bill was returned to the House floor in October; however, Congress was adjourned before final House approval could be given.

In the Council's opinion, the failure of Congress to renew the health planning program came as a surprise to the Department of Health, Education and Welfare and to national and local health planning staff. Many of the planning officials felt that the Administration had devoted more energy and resources to seeking passage of cost containment legislation than to seeking passage of new health planning legislation. HEW Secretary Califano, however, has now identified health planning as one of three major legislative objectives (the others being cost containment and the Child Health Assessment Program) in the 96th Congress.

Viewing the period of January to April, 1979, as critical for the health planning program, HEW has undertaken development of a new health planning bill. The Administration's new bill is expected to include strong certificate of need provisions, a program of decertification and an increased role for state government in the planning process. HEW officials have indicated that a strong lobbying effort will be mounted to secure Congressional approval of the Administration's proposals. To this end, Health Systems Agencies will be requested to contact individual Congressmen at the local level, while efforts will be made to secure support from such organizations as the National Association of Counties, the National Governors' Conference, and the National League of Cities.

The Council's Ad Hoc Committee on Health Planning has reviewed previously sponsored AMA amendments to P.L. 93-641, and has developed recommendations concerning these and several new amendments. These recommendations are now being reviewed by the Council on Medical Service, and will be transmitted to the Council on Legislation for review and subsequent introduction in the new Congress at the appropriate time.

### Present Status of HEW Health Planning Activities

As of November 1, 1978, the Department of Health, Education and Welfare had fully designated 165 (of 205) Health Systems Agencies. Additional time has been granted to 28 other HSAs to complete designation requirements. Designation has been withdrawn from Health Systems Agencies in Puerto Rico and Los Angeles, California, and replacements have not been designated for these agencies. Most of the HSAs (180) are private non-profit agencies, four are units of local government and 21 are regional planning bodies. Approximately 60% of the HSAs are former Comprehensive Health Planning Agencies, with the same key staff carrying over.

Federal funding to HSAs increased from $64 million in 1977, to $107 million in 1978. Approximately 70 HSAs, serving large sparsely populated areas, received minimal federal funding of $175,000. Funding is based on population density and, unlike their urban counterparts, minimally funded HSAs do not receive matching funds from HEW. Excluding the minimally funded agencies, the average HSA received in excess of $473,000 during 1977.

All states and territories have established State Health Planning and Development Agencies (SHPDAs), of which 26 are located in state health departments; 20 in state health and welfare offices; six in Governor's offices and three in other arrangements. The Department of Health, Education and Welfare has fully designated SHPDAs in the states of Arkansas, Colorado, Hawaii, Kansas, North Dakota and Wyoming. According to HEW officials, the largest obstacle to further SHPDA designation is approval of state certificate of need (CON) legislation meeting the requirements of CON regulations issued in January 1977. The major concern of HEW is the absence of penalties in state legislation. Federal funding for SHPDAs has increased from $19 million in 1976 to $29.5 million in 1978.

HEW goals for fiscal year 79 include full designation for 195 HSAs, along with the majority of SHPDAs, provided that acceptable state certificate of need laws are approved. Other activities will include a limited performance review of 25% of the HSAs with detailed assessments deferred until 1980; greater coordination in state programs between the enactment of certificate of need (CON) programs, and the subsequent phasing out of programs under Section 1122 of the Social Security Act; and the implementation of a national appropriateness review program.

### National Council for Health Planning and Development

Three new members have been appointed to the National Council for Health Planning and Development as of September 1978. The new members are Robert L. Biblo, President of the Health Insurance Plan of Greater New York; Pete M. Mirelez, Chairman of the Adams County, Colorado Board of Supervisors; and Philip R. Lee, M.D., Director of Health Policy Programs and Professor of Social Medicine at the University of California. With the addition of Doctor Lee, there are currently four physicians serving on the National Council for Health Planning and Development. The new members were appointed by HEW Secretary Califano to replace two consumers and a hospital administrator. With the appointments, the hospital industry has no direct representation on the National Council. The AMA has previously provided nominations for the National Council and will, in all likelihood, do so again in the future as slots become available.

In order to discuss and advise on health planning issues in more depth, the National Council has rewritten its charter to allow formation of subcommittees. In September 1978, the National Council authorized creation of the following subcommittees; Subcommittee on Guidelines, Goals and Standards; Subcommittee on Administration and Implementation; and Subcommittee on Technology and Productivity. Each of the Subcommittees has identified specific work programs for 1979, and the National Council has requested that HEW provide resources for these activities. Currently, no appropriations are made to specifically fund the activities of the National Council, and the National Council has asked that HEW include such appropriations in new health planning legislation.

The National Council has expressed its intent to fully support new health planning legislation, and to continue to provide input to the HEW Secretary on federal regulatory activities.

### Liason with HEW

In November, 1978, the Ad Hoc Committee of the Council on Medical Service on Health Planning met with the newly appointed Director and Deputy Director of the Bureau of Health Planning of the Health Resources Administration/DHEW, to review discussions conducted with previous federal officials and to discuss federal health planning activities planned for the next few months.

The Health Resources Administration has recently undergone a reorganization which divided the old Bureau of Health Planning and Resources Development into two new units. The Bureau of Health Planning will retain responsibility for implementation of the health planning program with HSAs, SHPDAs, and SHCCs, and for the development of federal regulations. The newly created Bureau of Health Facilities, Financing, Compliance and Conversion will address four areas; facilities compliance, facilities financing, facilities conversion and energy policy and programs.

HEW officials indicated that the development of productivity standards, or concrete goals to be achieved by the health planning program, will assume priority over the next two to three years. In this regard, planning directives to HSAs and SHPDAs will soon require these agencies to focus their activities on such specific issues as mental health, preventive care and emergency medical services, after fulfilling their responsibilities to address the National Health Planning Guidelines. Assistance by the AMA in developing such planning program goals was solicited.

As noted previously, the Secretary of HEW has identified health planning as one of three major legislative priorities in the 96th Congress. The Council's Ad Hoc Committee was informed that HEW will seek support for the planning program from the Office of Management and Budget, will meet with House and Senate leadership, will encourage HSAs and SHPDAs to meet with state and local officials and members of Congress to strengthen political support at all levels, and will work with interested national organizations, such as the American Health Planning Association.

HEW officials also indicated that several sets of health planning regulations will be released over the next few months. Proposed regulations on appropriateness review, use of federal funds, and composition of HSA governing bodies had been suspended in anticipation of Congressional approval of new health planning legislation. Since that approval was not forthcoming, HEW will complete and publish the proposed regulations with intent to revise them in 1979, pending enactment of a new health planning law. Similarly, HEW plans to release draft National Health Goals and Sub-Goals prior to the end of 1978. Official publication of the National Health Goals and Sub-Goals will be preceded by a 45-day period of consultation, to be followed by a 60-day public comment period. The AMA, through the Council's Ad Hoc Committee, was invited to review the National Health Goals and Sub-Goals, and to provide input during the consultation period prior to publication of a Notice of Proposed Rule Making.

The Council believes that the meeting with new planning officials was informative and productive, and served to re-establish liaison, which had been disrupted by personnel changes at the federal level during 1978.

### Regional Health Planning Workshop

On September 19-20, 1978, the Council and its Ad Hoc Committee on Health Planning sponsored a Regional Health Planning Workshop in Atlanta, Georgia. This pilot workshop was undertaken to determine the level and effectiveness of communications between medicine and the network of HSAs and planning agencies at the state and local level, and to encourage more effective physician participation in health planning in those settings.

A total of 146 persons attended the Atlanta program. The participants represented state and county medical societies, and health planning agencies from HEW Region IV, which is composed of the states of Alabama, Georgia, Florida, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee and a portion of Virginia. The conference was co-sponsored by the Southeastern Association of Health Systems Agency Executives (SAHSAE), representing the 41 HSAs in the region. The program was jointly developed by the AMA and the SAHSAE, and each promoted attendance from respective constituencies. The major portion of the program was devoted to small, issue-oriented workshops. Members of the Council's Ad Hoc Committee and several physicians/consultants were paired with HSA executives in moderating the workshops. The program was arranged to enable each participant to attend each workshop.

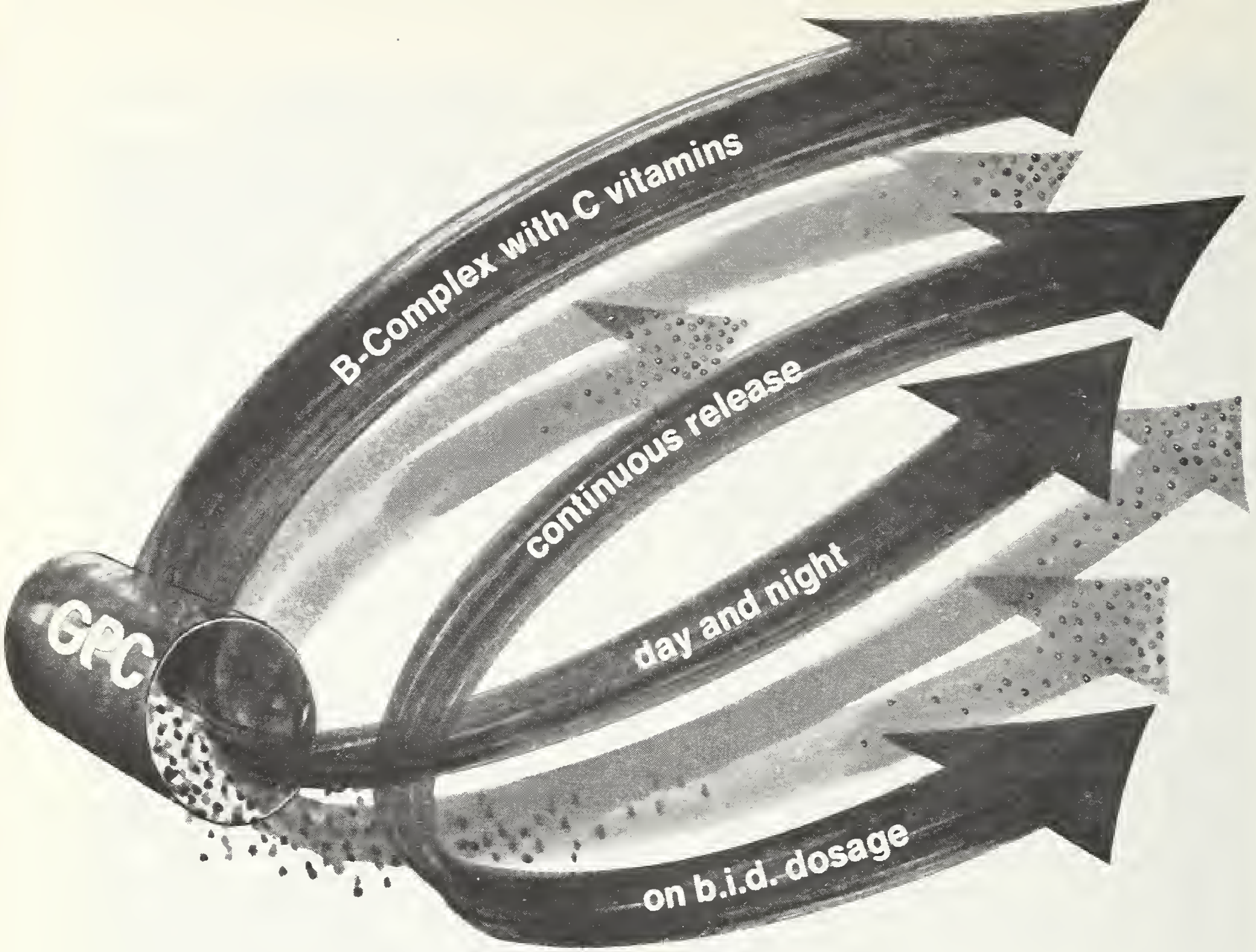
From observation, and from written evaluation forms, the Ad Hoc Committee believes the initial Regional Health Planning Workshop was a success, and that future programs of this nature can promote effective physician participation in the planning program. Based on experience with this first regional program, it appears that some state and county medical societies have not developed formal mechanisms to respond to planning activities. This was evidenced by a number of physicians who attended the program representing HSAs, which had no working relationship with medical societies. On the other hand, planners freely expressed the opinion that physician participation is essential to the health planning program.

The Council and its Ad Hoc Committee will conduct additional regional workshops in 1979.

### Federation Guidebook on Health Planning

Completion of major sections of the *Federation Guidebook on Health Planning* was postponed for several months during Congressional debates over renewal of P.L. 93-641. In the absence of renewal legislation, the Council's Ad Hoc Committee has decided to proceed with publication of completed sections of the *Guidebook,* which address (a) strategies for physician involvement in health planning and, (b) elements of plan development. It is projected that these sections will be published in late January 1979, with additional sections to be issued at a later date. These additional sections will analyze new health planning legislation—when enacted—and summarize federal regulatory activity to implement such legislation.

The Council on Medical Service and its Ad Hoc Committee on Health Planning will continue to monitor health planning activities and provide assistance to the Federation in this area.



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# The Center for Disease Control—1946-1976

HELEN O. NEFF

The Center for Disease Control (CDC), headquartered in Atlanta, Ga., is one of six major agencies of the U.S. Public Health Service (PHS). It was originally established as the Communicable Disease Center on July 1, 1946, as the first Federal Health organization ever set up to coordinate a national control program against a whole category of diseases. Its sphere was those diseases spread from person to person, from animals—including insects—or from the environment to man. Two important communicable diseases, tuberculosis and venereal diseases, were excluded initially. Separate control programs had existed for them for several years, both headquartered in Washington.

CDC was built around the nucleus of its immediate progenitor, the Office of Malaria Control in War Areas (MCWA), to which it owes much. MCWA, an emergency World War II organization, was initiated in March 1942, three months after the attack on Pearl Harbor. It was designed to control anopheline mosquitoes and reduce potential malaria transmission in extra—cantonment zones of military establishments and essential war industries. Counterpart activities within reservation limits were carried out by the War Department.

At the time, malaria was particularly endemic throughout the Southeast. In other respects, the region afforded favorable aspects for year-round military training and maneuvers and for the operation of war plants. Atlanta was selected for MCWA's home base because it was a conveniently central point of endemic malaria and was also the transportation hub of the South.

MCWA worked directly with State health departments through District (now Regional) personnel to effect maximum control of malaria with the least cost in manpower and materials. The States carried out the actual operations through their own administrative channels and under their own legislative responsibility. MCWA contributed trained personnel, specialized equipment, materials under wartime priority, and aid with Federal-State administrative and fiscal matters.

To do so, it assembled a multi-discipline staff to man its five divisions: medical, engineering, entomology, training, and administrative. Some of its specialists were retained at headquarters. Others were deployed to State health departments to provide supervision, coordination, technical development, field evaluations, training and training materials, and the necessary equipment and materials to be used by state-provided labor to bring malaria under control.

Although MCWA was set up originally to cope with just one disease, in 1943 it undertook measures against the mosquito *Aedes aegypti* in Hawaii and in port cities in southeastern United States to control dengue fever in Honolulu and to prevent the establishment of yellow fever in the United States. When DDT became available, it revolutionized malaria control procedures and enabled an attack on

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HELEN O. NEFF, Writer-Editor, Office of Information, Center for Disease Control, Public Health Service, U.S. Department of Health, Education and Welfare, Atlanta, GA.

another endemic vector-borne disease. In 1945 typhus control was added to MCWA's program, and rodent and rodent-ectoparasite control specialists joined the existing staff. As the war progressed, it became necessary to extend malaria control activities beyond the basic southern tier of 13 States and Puerto Rico. This was because many carriers were found among returning military personnel and prisoners of war throughout the country.

By then, there was also growing concern that returning military personnel might bring back exotic tropical infections, particularly parasitic ones. This prompted the American Society of Tropical Medicine to recommend that the Public Health Service establish a training program in the laboratory diagnosis of such infections. MCWA did so in 1945.

Some research was carried out during the MCWA years, primarily related to malaria and typhus control methodology, anopheline ecology,and the infectivity of imported malaria parasites. It was mostly on a cooperative basis with the National Institute of Health (then singular), the Tennessee Valley Authority, the Department of Agriculture, and university and State health departments.

By its very nature and purpose, MCWA was destined to pass into oblivion at the end of the war. However, during its short life span, it had met new challenges in a way that demonstrated the inherent wisdom and efficiency of attacking related health problems with teams of specially trained and equipped scientists whose activities were coordinated within a single organization. This experience had a direct bearing on the decision of the PHS to retain MCWA's personnel and facilities of proven worth for a peacetime operation with a much broader character.

It came about in this manner. Dr. Joseph W. Mountin, then Chief of the Bureau of State Services of the PHS, under which MCWA operated, envisioned several separate Centers to deal with such subjects as communicable disease control, environmental sanitation, arctic health problems, and so on. Each would be located away from the District of Columbia and each would provide highly specialized services and competencies that few states could afford to maintain on a day-to-day basis.

The existence of MCWA provided the first means to implement Dr. Mountin's concept. On July 1, 1946, Dr. Thomas Parran, Surgeon General of the PHS, redesignated MCWA as the Communicable Disease Center, CDC began auspiciously. MCWA's disease control specialists and administrative personnel were experienced and functioning as a team. The Atlanta headquarters were set up, some facilities already existed, and effective working relationships with State health departments had been established.

Primary activities included continued efforts toward vectorborne diseases. These included malaria eradication, typhus control, technical development and training in insect and rodent control methodology, studies on the relationship of flies to diarrhea and poliomyelitis, studies on arthropod-borne encephalitides. Also of concern were tropical,parasitic, and other diseases, such as amebiasis, schistosomiasis, filariasis, hookworm, yellow fever, dengue fever, and sandfly fever.

The Veterinary Public Health Division was established in 1947. And so many important zoonoses—diseases of animals transmissible to man—became a part of CDC just as Dr. Mountin had hoped would materialize. That same year, plague control activities were transferred to CDC. Bubonic plague was first recognized in North America in 1900 in San Francisco when the body of a Chinese who died of the disease was discovered in that city's Chinatown. It was this continent's fifth great pestilential disease; smallpox, yellow fever, cholera, and typhus fever were imported earlier. It was the only one of these that remains endemic to this day, having become widespread among wild rodents in the West.

A more comprehensive laboratory organization was developed with personnel and facilities for methodology research, reference diagnosis, evaluation of public health laboratories, provision for diagnostic biological materials, laboratory consultation, and surveys. Laboratory services were also provided to the new Epidemiology Division and to State health departments in the investigation of epidemics, as well as to CDC's other divisions as needed.

The Epidemiology Division was established to determine the extent of various communicable disease problems through analysis of statistical and epidemiological data, to recommend and evaluate control methods, and to render epidemic aid (on request) to States. A broadly-based training program supported by an audiovisual activity was created. Technical development activities were realigned to cover the ground broken by CDC's expanding concerns.

During the 1950's, the operational pattern of CDC evolved further in applied research, training, production of audiovisual materials, technical assistance and consultation, demonstration and epidemic aid. The famed Epidemic Intelligence Service, whose members are popularly known as the "disease detectives," was established in 1951. From the beginning, they were groomed to meet any epidemiological contingency in this country or abroad.

It was an era of great breakthroughs in the health sciences. New insecticides and antibiotics were formulated. Their numbers proliferated as a growing number of insects and pathogenic organisms developed resistance to them. The first National Conference on Hospital-Acquired Staphylococcal Disease was held at CDC in 1957 and the International

Conference on Nosocomial Infections in 1970.

Advanced laboratory techniques were developed that made it possible to identify many previously unknown strains and types of pathogenic microorganisms. CDC played a major role in adapting the fluorescent antibody technique to the rapid diagnosis of a number of pathogens. Virology came of age. Isolation and cultivation of the polio viruses led to the development of the Salk vaccine, with CDC assisting in the first field trials conducted in 1954.

On April 12, 1955, the vaccine was released for distribution. Two weeks later, six cases of polio were reported to the Public Health Service in children who had received one producer's vaccine. Within two days, CDC's Poliomyelitis Surveillance Unit was established. It immediately began summarizing all available information about the occurrence of polio and its possible association with vaccine and dispatching it daily to all State health officers and others responsible for controlling the disease.

More than 80 percent of the vaccine-associated cases reported were related to the one product, although it comprised less than 10 percent of the total vaccine distributed. It was withdrawnat once. The other manufacturers of vaccine were encouraged to stay in production and the immunization program proceeded.

It has been said—and probably rightly so—that the current control and regulation of chemical and such biological products as vaccines and antisera for the prophylaxis or treatment of human disease came about largely because of this incident and the also tragic "thalidomide affair."

After the immediate polio emergency subsided, reporting was limited to clinical, epidemiologic, and laboratory data on cases in vaccinated individuals only. Surveillance was maintained on the vaccine's safety and evaluation of its effectiveness. Laboratory diagnosis had progressed to the point where other viruses, such as those in the Coxsackie and ECHO groups, which produce a syndrome simulating poliomyelitis, could also be identified. Now it was possible to distinguish true poliomyelitis from its look-alikes, against which the vaccine was ineffective.

The role of CDC in a national health emergency was clearly established during this incident, setting a precedent to develop similar surveillance programs without delay when the need arose. Urgency called for the same prompt action two years later, when the new variant A2 Asian strain of influenza virus swept around the world.

The Asian flu pandemic of 1957-58 highlighted the value of global health activities. The United States had joined the World Health Organization (WHO) in 1948 to work with other countries toward winning the highest possible level of health for all people. Even before the Asian influenza pandemic, WHO had established a network for the study of influenza strains in virus laboratories all over the world. Serving as the Center for the Americas, CDC distributed sets of typing reagents for the Asian and older influenza strains, and also shared current laboratory "know-how" with more than 160 laboratories representing 32 different countries in the Western Hemisphere. WHO had also established an international intelligence network, of which CDC was likewise a member. From this dual vantage point, and calling on its earlier experience with surveillance and reporting on polio and other diseases, CDC issued frequent reports on the status of Asian flu. These were of great value to health workers here and abroad.

Practically all of CDC's operational services were put to work on the international health front, in one way or another, through WHO, the Pan American Sanitary Organization (then Bureau), and our own Department of State's foreign aid program. CDC had been a pioneer in training foreign health workers, particularly those from developing countries where infectious diseases were the major cause of death and disability and where advanced technology had not yet taken root. Now the philosophy behind CDC's assistance to State health departments was applied to all nations that sought its aid—to help them develop increasingly effective programs of their own for the prevention, detection, diagnosis, and control of infectious diseases.

By the end of the 1950's, CDC, in the fullest sense, was the national resource through which new areas of knowledge in communicable disease control developed by research and other investigative activities—its own and those of other institutions—were converted rapidly and effectively into usable forms for public health practice. It had acquired a multidiscipline staff, whose professional and technical personnel were recognized internationally as experts in their specialties.

The Venereal Disease and Tuberculosis Programs were transferred in 1957 and 1960 respectively, adding their own special dimensions to CDC's activities. Among these assets were the experience and skill accumulated by working directly with health departments in combatting these important person-to-person diseases, with their social as well as their medical aspects. They were to prove their worth again in the coming era of mass immunization campaigns.

Until 1960, when CDC's headquarter's complex adjoining Emory University in Atlanta's suburban northeast section was dedicated, its activities were carried out in scattered—and often "make-do" facilities—not only around Atlanta but in various field stations as well. Now functions that did not have a logical reason for being separated geographically came together.

For example, CDC's Bureau of Laboratories had started out with a general parasitology laboratory on the second floor of a building in downtown Atlanta in 1946. Its Malaria Blood Parasite Laboratory was set up to examine specimens from military men returning from stations in the Pacific during World War II who were known to have had malaria. The next year, recruitment started to staff a true communicable disease laboratory division. By 1949, there were five branches. The bacteriology, mycology, and parasitology branches were housed in remodeled buildings built for temporary use at the Lawson VA hospital in nearby Chamblee, Ga. The virus and rickettsia branch, organized primarily for the study of polio and murine typhus, was located in buildings formerly occupied by the Rockefeller Foundation's rabies laboratory, next to Gunter Air Force Base, in Montgomery, Ala. The western branch, which was activated when plague control activities were transferred to CDC in 1947, was located in San Francisco. The clinical pathology branch was established later in quarters adjacent to Grady Hospital in downtown Atlanta, where it was developed in cooperation with the public Grady Hospital and Emory University's School of Medicine.

Responsibility for the *Morbidity and Mortality Weekly Report* was transferred in 1961, adding new scope to CDC's surveillance activities and further strengthening the give-and-take partnership with the State health departments. It entails the weekly recording, analysis, publication, and distribution of data provided by State health departments and other sources concerning the occurrence of infectious diseases in this country. In addition, 121 major cities each week document the number of deaths from various causes.

Mass immunization campaigns came into being. Although the annual incidence of paralytic polio fell below 1,000 for the first time in 1961, epidemics were still occurring all over the country. Unvaccinated preschool children in low socioeconomic areas were the major victims. Columbus, Ga., was the first city to make a community-wide effort to wipe out the disease, with help from CDC, State, and private health agencies. Atlanta was first to use the newly-developed Sabin oral vaccine to avert a threatened epidemic. The incidence of paralytic polio fell from 13,850 cases in 1955 to 5 in 1975.

In 1962, Congress passed the Vaccination Assistance Act to help States and communities carry out intensive immunization programs against polio, diptheria, whooping cough, and tetanus, and other diseases as new vaccines became licensed. When funds were made available in 1963, CDC became responsible for administering the Act through project grants. By the end of the year, approximately 47 percent of the population was covered. Measles vaccine was added to the program in 1965 and rubella vaccine in 1969. CDC has published studies showing the massive economic savings estimated to have come from widespread, Federally funded use of the two latter. The saving in human suffering is immeasurable.

The Foreign Quarantine Division became a part of CDC in 1967, and because of rapid intercontinental transportation of people and goods, this oldest of public health activities has changed to fit the times. It is no longer practical or necessary to board incoming ships and planes routinely at ports of entry and inspect crews, passengers, and cargo. Today captains of intercontinental air and surface craft notify CDC by radio before arrival of any cause for suspicion on board. If there is none, they enter the country without delay. With the improved exchange of international epidemiological information and cooperation, the current approach is to detect and prevent the spread of disease by controlling it at its source. As an extra safety measure, CDC has established readiness programs to cope with the possible importation of such diseases as smallpox and cholera.

In 1966, WHO established a global program to eradicate smallpox everywhere within 10 years. With the Agency for International Development (AID) providing the funds, CDC gave direction to the program in 19 West and Central African countries. The procedures it worked out were so effective that the goal was reached in those countries well ahead of time. By the spring of 1976, smallpox had retreated to the almost inaccessible mountain fastnesses of Ethiopia. Vaccination teams were being airlifted by helicopter to effect total eradication. By this aggressive and relentless effort, mankind for the first time in history is deliberately eradicating one of the world's greatest epidemic diseases.

During the 1960's, CDC began its research in support of NASA's planetary quarantine activities. These resulted in the development of improved techniques for the microbial assay of spacecraft and environment in which they were assembled and tested. Subsequently, CDC handled all quarantine measures in connection with the moon landings.

CDC became the Public Health Service headquarters for the national laboratory improvement program, which was instituted in 1962. Special responsibilities for improving laboratory diagnostic services included standardization of tests, continuous evaluation of public health laboratories' performance, production of control and reference biological reagents, consultation, and training for laboratory workers in the latest diagnostic technics. In order to bring old and new outreach activities into one organizational unit, it established its Laboratory Consultation and Development Section. Various studies were demonstrating conclusively that a high percentage of clinical diagnostic tests—nationwide—

were erroneous. As a result, Congress passed the Clinical Laboratories Improvement Act (CLIA) of 1967. The Act made the Department of Health, Education, and Welfare responsible for regulating and licensing clinical laboratories transacting business in interstate commerce. HEW delegated the task to CDC, which now examines and licenses such laboratories as are not already accredited by professional bodies with standards as stringent, or more so, than those required by the Act.

Because of its broadened mission and to open the door for action in other areas, CDC became the Center for Disease Control on June 24, 1970. It had already outgrown its headquarters facilities, requiring them to be expanded by 105 percent, and had added an animal breeding and holding facility in nearby Lawrenceville, Ga., where standard and specific pathogen-free animals could be produced and other large ones maintained for studies.

The 1970's became another era of transition for CDC—this time from control of infectious diseases only to an involvement with preventive medicine in its broadest sense. Its programs continued to expand through natural evolution and the transfer of other programs.

The Nutrition Program was transferred in 1970 and its report on the 10-State Nutrition Survey was delivered to Congress in 1972. The National Clearinghouse for Smoking and Health was transferred in 1972, and the National Institute for Occupational Safety and Health in 1973. The Bureau of Health Education was established in 1974. By 1975, CDC's activities also included certain aspects of family planning, surveillance and investigations of congenital defects, leukemia epidemiology, lead-based paint poisoning, urban rat control, and prevention of dental disease.

CDC started as a field station of the Public Health Service in 1946, became a Bureau in 1968, and a full-fledged agency in 1973. Its growth is both a continuum and a maturing of its earliest traditions, many inherited from MCWA. It will continue to flourish as long as it provides leadership and direction to programs and activities designed to improve the health of the people of the United States by preventing or controlling diseases, improving laboratory performance, and assuring—insofar as possible—safe and healthful working conditions for all working people.

### Men Who Have Headed MCWA and CDC

| | | |
|---|---|---|
| 1942-43 | Dr. Louis L. Williams (MCWA) | Brothers |
| 1943- | Dr. C.L. Williams (MCWA) | |
| 1944-46 | Mark D. Hollis (engineer). In 1970's was Chief, Department of Engineering and Environmental Science, PAHO, Washington, D.C. | |
| 1947-51 | Dr. Raymond A. Vonderlehr (dec.) | |
| 1952-53 | Dr. Justin M. Andrews (scientist, dec.) | |
| 1953-56 | Dr. Theodore Bauer | |
| 1956-60 | Dr. Robert J. Anderson | |
| 1960-62 | Dr. Clarence C. Smith | |
| 1962-66 | Dr. James L. Goddard | |
| 1966-77 | Dr. David J. Sencer | |
| 1977- | Dr. William H. Foege | |

EDWARD A. KAMENS, M.D.
President

# EDWARD A. KAMENS, M.D.

**Born:** Russia, February 13, 1923

**Education:**

Grammar School: The Eliza Bowman Missionary School, Cuba

High School: Bassick High School, Bridgeport, Connecticut

College: The Johns Hopkins University, Baltimore, 1940-1943
1st Sgt. Military Police 1943-1946, U.S. Army
The Johns Hopkins University, 1946-1947, B.A.

Medical School: University of Vermont, Burlington, Vermont—M.D., June 1951

Surgical Internship: Kings County, Brooklyn, New York—July, 1951-July, 1952

Surgical Residency: Combined Program, Maimonides Hospital,
(Downstate University of New York Affiliation)
Brooklyn, New York and Bronx Municipal Hospital Center,
(Albert Einstein College of Medicine) Bronx, New York, July, 1952-July, 1956

**Certifications:**

Diplomate National Board of Medical Examiners, 1952

Diplomate American Board of Surgery, 1957

Fellow, American College of Surgeons, 1962

Fellow, International College of Surgeons, 1965

**Practice Experience:**

Private Practice of General Surgery since 1956

Member of Active Attending Staff, Bridgeport Hospital

Former Chairman (Voluntary) Department of Surgery, Park City Hospital, 1959-1975

**Memberships—Professional Associations:**

Bridgeport Medical Society

Fairfield County Medical Association: Past President; Past Chairman, Board of Trustees

Connecticut State Medical Society: Former Councilor and Vice-President; President-Elect, 1978

American Medical Association

American College of Surgeons

International College of Surgeons

**Past Service Activities:**

American Cancer Society, Bridgeport Chapter—Past President

Comprehensive Health and Planning Agency, Bridgeport, Connecticut—(B Agency)

Board of Trustees, Southwest Connecticut—Health Systems Agency

Member Task Forces and Groups, Southwest Connecticut
Health Systems Agency and Health Systems Plan Committee

American Cancer Society, Connecticut Division: Board of Trustees

Medical Society Representative to Connecticut Family Health Plan
Board of Trustees and Executive Committee

Connecticut Medical Institute, Board of Trustees

Committee on HMOs, PSROs and liaison with Medicare Part B Carrier of
State Medical Society

Legislative Committee State Medical Society

Board of Trustees, COMPAC

**Awards:**

Woodbury Award, University of Vermont, 1949

Elected to Sigma Xi, Honorary Academic and Research Society, 1951

New York Academy Sciences, 1955

Awarded Ettinger Fellowship, American Cancer Society, Bridgeport, Connecticut, 1975

**Governmental Commission:**

State Health Coordinating Council

State Health Plan Committee

Committee on Structure and Relations with other State Agencies

# Inaugural Address of Edward A. Kamens, M.D., Incoming President of the Connecticut State Medical Society

I am honored to assume the role of President of the Connecticut State Medical Society. This office has grown in importance over the years by virtue of the tireless efforts of my predecessors, and I shall attempt to follow the fine example they have set.

This Society is an excellent example of representative democracy. It should be of comfort to all physicians in this State to know how conscientiously the House of Delegates deliberates and establishes policy; how well the Council and the committees of the Society carry out their interim roles; and, above all, how well Mr. Timothy Norbeck and his staff implement the policy established by the membership.

The President's role in our Medical Society is less well defined and is often subject to modification by events surrounding his or her term of office. Mainly, however, the President has functioned as spokesperson for organized Medicine in our State, and I feel it important that you know my personal frame of reference as it affects that role.

Events of recent date have been moving so rapidly, and criticism has been heaped upon us in such quantity and at such a rapid rate, that I am afraid that we as a profession are growing weary of the constant need for rebuttal.

We are continually being criticized despite the fact that we are trying our level best to dedicate ourselves to the primary tasks of our profession, and we appear ineffectual in our response to what we feel is unfair criticism.

We have become favorite targets of journalists and editorial writers who portray us as insensitive, unfeeling and crass technicians whose sole concern is material gain.

Television reporters consider us worthy subjects for "exposés," and Secretary Califano blames us for all of the maladies of the health care system because we admit patients and order tests and medication that create expenditure of health care dollars.

Even the Federal Trade Commission's Mr. Pertschuk finds us objectionable because our authoritative style exerts undue influence on the public. He would supplant this with a system that encourages physicians to advertise and destroy physician peer review and the discipline by which we govern ourselves.

Legislators shy away from us because of our arch conservative image, but suddenly recognize that we represent a broad spectrum of political opinion only at election time.

How strange all of this seems to physicians who began their professional careers full of idealism and hope. We set exacting goals and tasks before us and bound ourselves by oath to carry them out to the best of our ability.

When we fail to accomplish all of these to perfection, either because of extrinsic circumstances beyond our control or because of normal human failure, we are often subjected to ridicule and condemnation.

Under this constant barrage of criticism, no wonder we occasionally doubt ourselves. No wonder we sometimes respond in anger and no wonder we regretfully stoop to righteous indignation.

We do not nor shall we ever attempt to silence all our critics, since some of their criticism is valid and merits our most thoughtful consideration and corrective action. There are other of our critics, however, whose criticism is vindictive, destructive and unwarranted. These are the most difficult with which we have to deal.

But, *Veritas vos liberabit*—the truth shall set you free. I hold these truths to be self-evident.

It is we who render care to the sick.

It is we who suffer with our patients through tragedy and rejoice with them through triumph. And when we meet with failure

It is we who subject ourselves to self-examination and self-criticism and rededication to improvement.

It is we who establish standards of care within our profession and our hospitals and dedicate ourselves to the protection of the public good.

It is we who devote ourselves to a lifetime of learning and self-improvement.

It is we who after long and arduous days volunteer endless hours to committee assignments for Rehabilitation Centers, Cancer Societies, PSRO's, Data Gathering Centers, Health Planning Committees, and an endless list of others where our talent may be of value.

And it is we who have contributed financially to our Medical Schools and Scholarship Funds, so that those of limited means who wished to enter the medical profession would find an element of support within its ranks.

One other truth I hold self-evident. With all our faults, this profession in overwhelming numbers is composed of dedicated, dutiful, disciplined, devoted, decent human beings.

That is the message I should like to bring to all my colleagues during the coming year, and that is the message I should like you to bring to everyone in your daily contacts, and that is the message I should like the public to hear.

For, to paraphrase the words of that ancient sage, Rabbi Hillel, "If we are not for ourselves, then who shall be for us; and if we are only for ourselves, then what are we; if we don't stand up and say it now, then when are we going to say it?"

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## NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS.** This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:
J. Alfred Fabro, M.D., Editor
*Connecticut Medicine*
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# in Brief

## A summary of AMA, medical & health news

American Medical Association/535 North Dearborn Street
Chicago, Illinois 60610/Phone (312) 527-1500/TWX 910-221-0300

**The Voluntary Effort** was successful in its 1978 goal of reducing the rate of increase in hospital expenditures, the Congressional Budget Office told the House Committee on the Budget. However, the CBO said that the VE's goal of a 2 percentage point reduction in 1979 probably won't be achieved. The CBO added: "The projected general inflation rate of 8.4% during 1979 and other cost-increasing factors will make the rate of increase in hospital costs too high for the VE to reach its goal." The VE was initiated in December 1977 by the American Hospital Assn., the Federation of American Hospitals, and the AMA.

**The introduction in state** legislatures of a model bill that would allow a coroner's physician or medical examiner to remove the pituitary gland at the time of autopsy is urged by the AMA. The bill was developed following AMA House of Delegates action at the 1978 Interim Meeting to encourage increased collection of the human growth hormone. The model bill would apply only in cases where autopsies are required by law, unless the decedent or relatives have indicated disapproval. The hormone, supplied free to physicians, is in very limited supply, according to the National Pituitary Agency.

**Many state medical** associations have expressed interest in scheduling AMA Official Family Briefings during their 1979 annual meetings. The briefings began this year as an extension of the Board of Trustees Visitation Program, which has been conducted for many years and under which AMA officers and trustees visit the annual meetings upon invitation from the state associations. The purpose of the Official Family Briefings is to promote a private, informal exchange of information on significant health care issues between AMA officials and state association leadership. For more information contact the Office of EVP, AMA Headquarters.

**"Indications for Aorto-coronary** Bypass Surgery," a report prepared by the Council on Scientific Affairs after study by a panel of consultants, was approved by the AMA Board of Trustees. The report will be submitted to the House of Delegates at the 1979 Annual Meeting with the recommendation that it be approved for publication as an AMA statement. The Board commended the council on its program to explore controversial subjects and on its use of panels of consultants in the study of the subjects.

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# Reflections from the Dean's Office

## And Ne'er the Twain Shall Meet?

ROBERT U. MASSEY, M.D.

It was recently my privilege to visit several medical schools and biomedical research institutions in Hungary and in Yugoslavia. The cultural and scientific heritage of these two nations is different, and their recent political histories, while both shaped by socialist ideology, are unlike in spirit and have moved in divergent directions. However, what they have in common is only a decade, more or less, of development in modern biomedical research.

Lajos Alföldi, the director general of the new and well-equipped Biological Research Center in Szeged, said that, for the most part, before 1970, biology in Hungary had been stuck at the descriptive level. To catch up, the leaders of the Academy of Sciences determined that the best plan would be to send bright, young men and women to modern research laboratories outside Hungary to become familiar with the concepts and skilled in the techniques of molecular biology. Consequently almost all of the scientists working at the Center in Szeged have had extended experience working with investigators in the United States, Canada, the United Kingdom, West Germany, France, or Russia. Friendships developed and collaborative work continues. Much of this effort was funded by the United Nations Development Program; it is now bearing fruit in that the research presently going on is as advanced as any in the established centers of the West. The investigators are young, enthusiastic, and terribly proud of what they have accomplished for themselves, for Hungary, and for science.

Dr. Ferenc Antoni, Rector of the Semmelweis Medical University in Budapest, said that "in science there are no borders." He added that our problems had no borders either, that they were the same everywhere: insufficient support, complications from bureaucracies whose powers increased exponentially, and the recurring popular mood of antiscientism. Even though he knew no good solutions, he was optimistic that the scientists and humanists would bring the world together, and that man's condition would improve because of the free exchange of people and ideas in spite of political barriers.

In Yugoslavia research seemed on the whole less well supported, but enthusiasm was high, and the movement of people in and out of the country was easier. The University of Connecticut and the University of Belgrade have had a collaboration agreement since 1977, and the possibilities for exchange of faculty and students are limited only by the availability of travel funds. The Research Institute in Belgrade has kept a position open for two years for an immunologist who is completing her doctorate at the University of Washington. The University of Zagreb Medical School is working with the University of Hamburg Medical School on curriculum reform, and would like to share experiences with the University of Connecticut School of Medicine on problems in student admissions, integration of basic science and clinical work, and evaluation of student performance. A hospital director wanted to know what we were doing to influence specialty and geographic distribution of physicians, and how we limited the demand for medical services.

There is, I suppose, the danger that too much talking and working together will make us all alike, that the whole world will become one continuous Los Angeles with no escape from freeways, television, shopping malls, and research centers; that the diversity achieved on the Tower of Babel by the confusion of language will be lost. That seems to be a gloomy end to our colorful history, more like a whimper than a bang, but I doubt that we know enough about the laws of social evolution to predict, prevent, or to cause such a denouement. Isolation, parochialism, suspicion, and ignorance, however, have rarely led to a beneficient outcome. It may be that we can learn to preserve and cherish our differences while accepting our shared condition and delighting in the transcendent nature of truth.

Several of my East European colleagues seemed eager to talk about these differences, perhaps to try to exorcise their power. They pointed to the ancient origins, to Constantine's division of the Empire between East and West, or to the furthest westward advance of the Turks.

Even Christianity had not unified, because, although the substance was the same, the forms were different. But in science there is objective truth, or at least confidence in it, a common language, common forms, and even common architecture. A telephone call to review data puts Anikó Venetianer's laboratory in Szeged next door to that of her colleague in Bethesda. They will soon publish another paper together on glucocorticoid receptors. Enough linkages like this could diminish the force of the old historic divisions; enough liking and respect between individual men and women could make the old hostilities seem silly.

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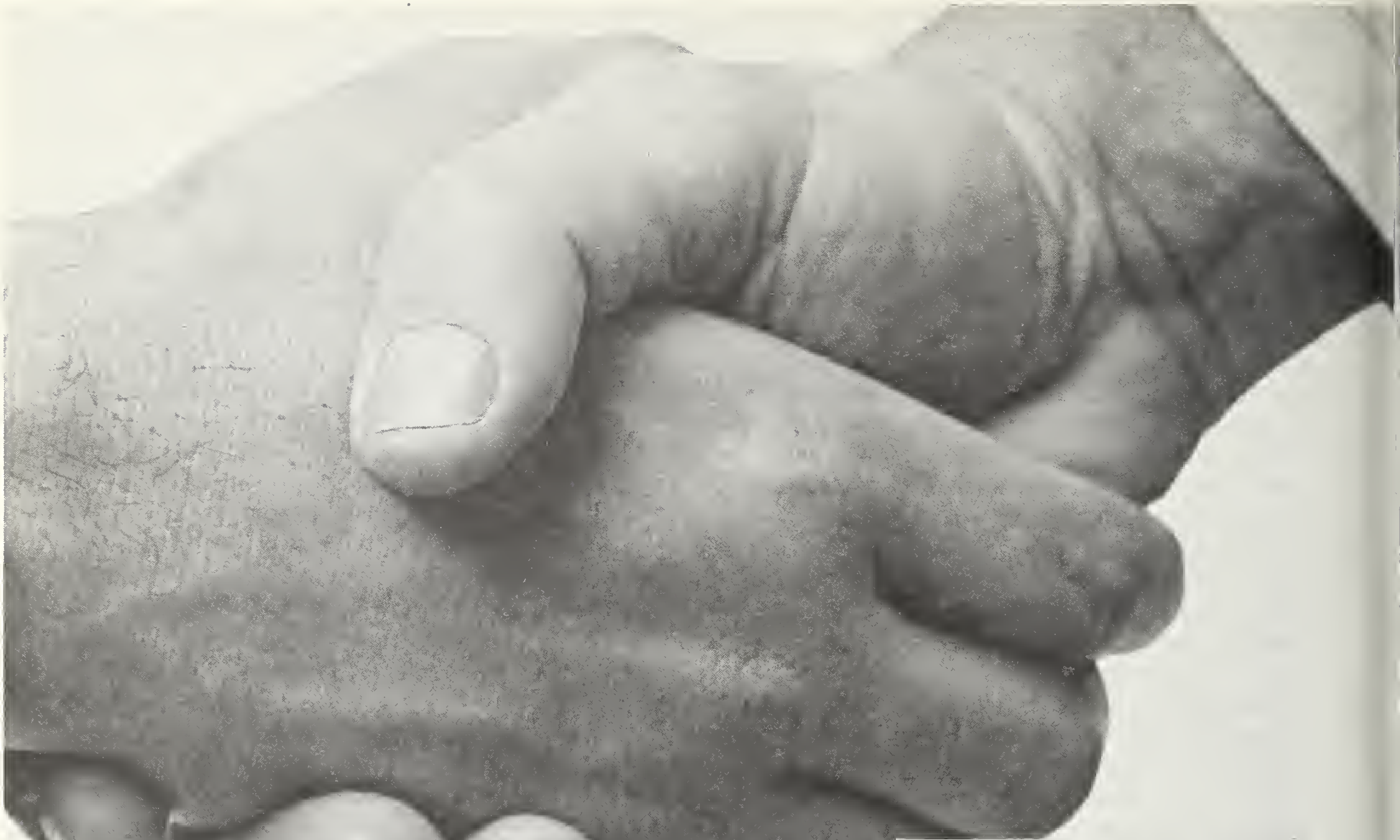
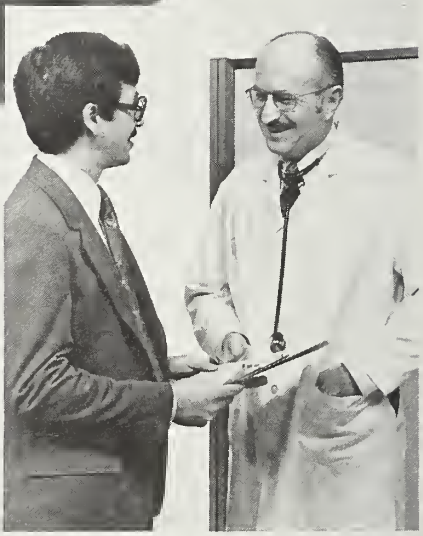
ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.





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# The Physician's Duty to Disclose: The New York Cases II

JOSEPH M. HEALEY, J.D.

The cases of *Becker v. Schwartz*[1] and *Park v. Chessin*[2] both revolve around the physician's obligation to disclose information to the patient. In both cases, the patients allege that the communication of insufficient or inaccurate information was a key element in their decision to give birth. Both allege that if adequate and accurate information had been communicated, they would not have allowed the birth of a child with Down's Syndrome in one case or with polycystic kidney disease in the other. The families seek to place the financial burden of the costs of care and support for the children on their respective physicians for their failure to communicate properly. These two cases are of concern to physicians who argue that the cause of the transmission of the genetic diseases or conditions rests with the parent and not with the physicians in the cases. They argue that the physicians should have no responsibility in these cases. The responsibility should rest entirely with the parents.

Such a conceptualization of the issue misses an important element of the families' claims. The point is not what caused the genetic diseases or conditions to exist, but rather whether the physicians violated their duty to provide information to the couple making a decision about procreation. Did the physicians in the first case have a legal obligation to disclose to the pregnant woman: (1) that she was at increased risk for having a child with Down's Syndrome since she was over 35; (2) that amniocentesis was available to detect the presence of Down's Syndrome; (3) that, if the child had Down's Syndrome, then abortion was available to her. In the second case, did the physicians fail to accurately describe the hereditary nature of polycystic kidney disease? These questions remain for determination at trial of the cases on the merits. It will be interesting to see how the trial court approaches the determination of what information was material to the families' decision to beget a child and who had the obligation to provide it. Clarification of this issue and of the many areas of the cases where factual information is not entirely clear will provide us guidance in understanding the impact of these cases on other physicians.

At a very minimum, physicians should regard these cases as a reminder of the importance of communicating information to patients. The difficulties are quite clear. Nonetheless the communication of information is an important foundation of the exercise of consent. In Connecticut, we have had no recent case answering the question whether a physician needs to disclose what a reasonable physician should disclose in the same or similar situations or what a reasonable patient needs to know.[3] Physicians should be aware that this ambiguity could result in problems for them.

The New York Court of Appeals refused to allow any recovery by the children in these cases for being born with the respective conditions. In so holding, the Court overruled a finding by a lower court that children possess a constitutional right to be born whole, without defect or injury. The Court found no basis for such a claim in any source and rejected it without hesitation. The disastrous implications of recognizing such a right should be obvious to all.

In recent weeks, attention has been called to the fact that the Becker child was put up for adoption and has been adopted. Such an act is likely to have no influence on the claims of the parties, except to cut off the point at which damages could be awarded to the Becker family at that date.

These cases are another example of the wide range of problems existing in the area of reproductive decision-making. They remind us all too well that physicians and patients need clearer delineation of their rights and responsibilities. They also remind us that such delineation is a long and difficult process.

---

JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

*I would like to express my gratitude to William F. Dowling, Esquire, Director of the Division of Criminal Justice Services, Bureau of Prosecution and Defense Services, State of New York, who made available to me copies of the cases.*

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WORKING FOR ALL....

This year is a very special one because it marks the 50th anniversary* of the first prepaid hospital plan in the country — the forerunner of the Blue Cross and Blue Shield concept as it is known today.

In Connecticut, the Blue Cross and Blue Shield Plans are not quite that old, but their work — for many years independent of each other, and today working as one — have always had a twofold purpose:

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Here in Connecticut, a plan for hospital care was incorporated in September 1936, with the first group enrolled six months later.

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# EDITORIALS

## Caffeinated Drinks: A Public Health Problem?

Caffeine is coming under increasing suspicion regarding its desirability as an additive to soft drinks consumed by children.

Last year over 30% of all coffee consumed in the U.S. was decaffeinated. The 3,000 tons of caffeine extracted annually to manufacture decaffeinated coffee for the benefit of the middle-aged and elderly, are used to caffeinate "soft drinks" largely consumed by the young. Four billion gallons of these drinks are consumed in the U.S. per year and they are the main source of caffeine for children and teen-agers.

Depending on individual susceptibility, it does not require large doses to produce caffeinism in the non-habituated, with a variety of symptoms that include agitation and irritability. This may account for the rapid rise in the consumption of decaffeinated coffee which is something of a national phenomenon. The demand has increased 700% since 1958 and by 60% since 1972. Apparently more and more adults feel that caffeine *does* affect them adversely.

While caffeine can certainly not be singled out as a causative agent for the hyperkinetic syndrome, it cannot be ignored either. Like the rising nicotine and alcohol use among the young, the over-consumption of caffeine by soda-guzzling children poses a potential public health problem; moreover compared to smoking and liquor, caffeine use extends downwards to far-lower levels, to grade schoolers and even the kindergarten set. In these children, if calculated on a weight related basis, the caffeine intake can easily reach levels corresponding to six to eight cups of coffee in adults. Some paradoxical therapeutic claims for coffee notwithstanding, caffeine *is* a stimulant of the central nervous system, shortening reaction time and increasing motor activity. In the foreground of its effects are agitation and restlessness, and as far as sleeping is concerned, in children it creates not so much inability to sleep, as an effect on the *depth* of sleep, which in turn affects the child during its waking hours.

Hypersensitivity to caffeine exists in some individuals, but lesser adverse reactions to it are among the most common food sensitivities. They may be especially manifest when caffeine is used in large amounts. It has been demonstrated objectively, by giving caffeine and placebo solutions via stomach tube, that gross symptoms can be produced including disabling tachycardia and palpitation.[1] Caffeine consumed by those who are susceptible, or its over-consumption, can also trigger severe anxiety neuroses. Greden[2] reported a number of cases related to an excess of coffee consumption, though adults often express disbelief that coffee could have anything to do with their symptoms. Caffeine in an amount corresponding to ten cups of coffee over several hours, has recently been described[3] as producing delirium and tremulousness in an adult, while smaller amounts may cause "dangerous sensory and motor disturbances."

Caffeine ingestion has long been known to predispose to extrasystoles,[4] and a study by Robertson[5] confirmed that even 200 to 300mg of it—that is the equivalent of 2-3 cups of coffee—can lead to major physiological changes in normal adults, such as an increase in the excretion of catecholamines. On general pharmaceutical principle, one can expect a greater level of effects in children, and particularly in those sensitive to it.

In a survey among "hyperkinetic" children in New Haven nearly all were found to be consumers of caffeinated drinks. The fact that to some extent this applies to calm children as well, does not speak against neurotropic effects of caffeine in the first group, since sensitivity and response to it vary greatly from individual to individual, probably more among children than among adults. Quantitative histories elicited from parents in this respect tend to be unreliable because of some awareness on their part that the questioner may disapprove of giving "cola" drinks to children.

In view of the pharmacological effects on the cortex, it is doubtful whether it is advisable to let children consume freely and ad lib caffeinated drinks, and it would seem particularly undesirable to allow them to have "cola" drinks in the late afternoon and evening, since caffeine has a half-life of four to ten hours in the blood circulation.

In a report recently released by an advisory panel to the Food and Drug Administration, some panel members stated that it was prudent to assume a potential health hazard in caffeinated drinks, particularly for children; others felt that more research was needed, before a far reaching decision could be made to remove caffeine from cola drinks entirely.

Meanwhile physicians, when faced with such symptoms as agitation, irritability, palpitation and others suggestive of caffeinism, should not underestimate the potentially noxious effects of caffeine on the cerebral cortex of those susceptible to it, particularly children.

Hans H. Neumann, M.D.

*Medical Director,*
*New Haven Health Department*

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## The Journal—1979

We seem to have developed a format for the Journal that is satisfactory to the Editorial Board, to the Council, House of Delegates, and Membership: (1) a scientific section, (2) a section for Society business with input from the A.M.A., and (3) a nonscientific section for subjects related to medicine and the delivery of health care.

This last is not limited to socioeconomics, but includes law, ethics, government, and the like, especially issues related to medicine in our own state. Because specialists in these fields are not aware that we are interested in publishing such articles in the Journal, I must solicit them. I repeat the obvious—that we all receive a surfeit of scientific journals—many free, some excellent, Also obvious, however, is the ever increasing importance of the nonscientific but medically related factors in our daily professional lives, too little information of which we receive in the average medical communication.

I have just made arrangements for Joseph M. Healey, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, to write a monthly column on medicolegal subjects. Before coming to Connecticut, he worked with William Curran, J.D., LL.M., S.M.Hyg., who writes Law-Medicine Notes in the *New England Journal of Medicine.* The Connecticut Hospital Association is also going to contribute a regular column about hospital subjects relevant to our membership. I am preparing a special supplementary issue on medical ethics, guest-edited by Stuart Spicker, Ph.D., Associate Professor of Philosophy at UConn, financed by a grant from the Connecticut Humanities Council. Though we are doing more than the average journal on such subjects, we wish to do even more, especially about the Connecticut scene. I am publishing here a brief table of the contributions made by the several largest institutions in the state during the last three years. Yale and UConn contribute generously (the disparity in the figures between the two is explained by the size of the respective faculties). Dr. Bob Massey continues to demonstrate in his monthly page those ideas that make him an outstanding dean largely responsible for the increasing stature of UConn among medical schools in the country.

| *Articles Published by:* | *Total Number of Articles* | | |
|---|---|---|---|
| | *1976* | *1977* | *1978* |
| Yale University | 37 | 42 | 28 |
| University of Connecticut | 17 | 22 | 13 |
| Hartford Hospital | 9 | 5 | 5 |
| Norwalk Hospital | 2 | - | - |
| St. Francis Hospital | 2 | 4 | 1 |
| Hospital of St. Raphael | 1 | 3 | 1 |
| Bridgeport Hospital | 1 | 2 | - |
| Stamford Hospital | - | - | 1 |
| St. Mary's Hospital | 2 | - | - |
| Waterbury Hospital | - | 2 | 1 |

This emphasis on larger institutions does not imply disregard of smaller institutions. I welcome more contributions from them. I must also mention the quality and provocative ideas expressed by our President, Dr. Jerome K. Freedman, two of whose monthly pages were reprinted in national medical papers, *Medical Tribune* and *Health Care Week.* Also, the *AMA*

*News* reprinted an editorial published in the September issue of *Connecticut Medicine* by our staff executive Robert J. Brunell, who reported his favorable reaction to the democracy exemplified in AMA conventions, compared with those of the National Education Association which he had attended while on the staff of the United Federation of Teachers in New York City. Dr. Sherwin Nuland, our new Literary Editor, is making a definite contribution to the Journal.

We are increasing our liaison with our larger institutions through members on the Editorial Board. Dr. Howard Wetstone will act as a catalyst, as his friends know, to increase contributions from the Hartford Hospital. Dr. Carl F. Hinz, Jr., Associate Dean for Academic Affairs, UConn School of Medicine, will do the same at UConn. Dr. James D. Kenney, New Haven, newly appointed Associate Dean for Continuing Education at Yale University School of Medicine, is being nominated by the Council at this meeting; if elected, he will promote even more input from Yale. Dr. Joseph Bove, Professor of Laboratory Medicine at Yale, guest-edited the April issue devoted to "Transfusion Topics—1979," a most important subject to all physicians. I must include the contribution of Harvey Berger, who while he was a student at Yale and now as a Fellow in Radiology there, has been instrumental in soliciting articles in this important and expanding field for the Journal. He illustrates a void in our Society organization, however—lack of formal student and resident participation in our Society organization as is being done so successfully in the A.M.A. The Council is addressing this. He was on the Editorial Board last year, but cannot be continued as classified as a student member, resident or Fellow. We shall, however, maintain a close relationship with him.

One subject worth mentioning is that as we branch out into nonscientific issues, we shall encounter ideas that are controversial, especially medico-legal, and recently the Federal Trade Commission. Though it is important and necessary to keep the members informed, our legal counsel advises against publishing anything being litigated or coming within the jurisdiction of the F.T.C. Also it seems good policy to publish articles and ideas by critics, especially those who agree with and are supportive of the principles for which our profession stands. It is even worthwhile at times to publish selected unfriendly articles, for how else can we respond or plan if we do not know what it is they criticize and advocate?

We were all saddened by the recent death of Dr. Stanley B. Weld, founder and long time Editor of *Connecticut Medicine* and emeritus member of the Editorial Board. I never met him though we corresponded frequently. He gave me support and made helpful suggestions. I shall miss him.

I do want to emphasize that publication of articles, editorials and all other material, including advertisements, does not imply approval by or policy of the Journal or the Society unless so stated. The Journal is open to all members in its letters-to-the-editor column.

The Journal belongs to the members. I welcome suggestions and criticisms, particularly if constructive. The content of the Journal must adapt to the rapidly changing conditions. We are trying to do so.

Fred Fabro, M.D., *Editor*

## Artificial Pancreas May Aid Diabetics

Researchers are moving ahead on perfecting a vest pocket artificial pancreas capable of normalizing blood glucose levels in diabetics, says a report in the Medical News section of the January 19 *Journal of the American Medical Association.*

Experimental devices now being developed would be carried or worn by diabetics. Even more exciting, says the JAMA report, is the possibility that research now under way will result in a totally implantable artificial pancreas, able to sense blood glucose levels, compute individual insulin needs, and automatically inject the hormone, all in a self-contained, miniaturized package.

At least six major research centers from Toronto to New Mexico and several in Europe are working on some aspect of the artificial pancreas. The vest pocket version of the device, known as an open loop system, is receiving the most attention because such an external system is within the range of current technology, the article says.

An open loop artificial pancreas generally includes a special micropump, an insulin reservoir, a power source, and a minicomputer preprogrammed to maintain a steady basal insulin flow rate as well as to provide extra insulin at mealtime. The flow rate would be determined individually for each patient.

Large bedside units have been manufactured to serve the latter purpose, as well as to inject the insulin, and 11 such units are in experimental use in North America.

"Experts generally concede (although there is some serious debate) that the complications associated with diabetes—kidney disease, diabetic retinopathy (eye problems and blindness), atherosclerosis, and heart attacks—are a result of inadequate control and wild swings of blood glucose levels," the article says. "If successfully developed, the artificial pancreas will provide precise control of these levels."—*New York State Journal of Medicine,* March 1979.

# FROM THE EXECUTIVE DIRECTOR'S OFFICE

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## Council Meeting

Wednesday, March 28, 1979

### Attendance

Present were: Drs. Freedman, Kamens, James, Backhus, Spitz, Ragland, Jr., Friedberg, Hess, Fabro, Canzonetti, Cramer, Van Syckle, McGarry, Sadowski, Anderson, Magram, Eslami, Krinsky, Zlotsky, Beck, Horrax, J. Barrett, Parrella, Tierney, F. Barrett and Sonnen.

Also present: Mr. Tomat (FCMA), Mrs. Lindquist, Mr. Brunell, Mr. Sweeney and Mr. Norbeck.

Absent were: Drs. Whalen, Jameson, Rosenthal, Shenker and Bates.

### Approval of Minutes

It was VOTED to approve the minutes of the meeting of February 8, 1979, as published and distributed.

### Reports from Physicians Serving on State and Federal Agencies

NHI—Orvan W. Hess briefly discussed the subject of national health insurance and mentioned that the situation was changing almost on a daily basis. He pointed out that there was increased sentiment in the Congress for some type of catastrophic health insurance plan and that he would have more to report on NHI as the situation intensifies. State PSR Council—Isadore H. Friedberg reported that communications had been established with the four PSROs and that a Medical Advisory Group had been developed. SHCC—Edward A. Kamens mentioned that many changes were being drawn up based on the many recommendations received from CSMS and other organizations. He also discussed the AMA Area Meeting to be held in Washington in late April. It was agreed that pertinent items to be discussed with the Connecticut Congressional delegation would include inflation, bureaucracy and regulations, catastrophic health insurance and the enormous costs involved in any new comprehensive insurance plan. PSRO—Andrew J. Canzonetti reported that the PSRO funding levels have been reduced for costs of review and administration. He also pointed out that Governor Grasso has not yet appointed a physician to the Connecticut Commission on Hospitals and Health Care, and he plans to submit another letter to her in April urging a prompt appointment. HSA—Edith M. Beck mentioned that a sub area Council was formed in Greenwich and that subsequently the HSA I copied the effort with the formation of its own sub area Council. Legislation—James W. Tierney reported on several legislative bills which interested the Society and pointed out that no final action has yet been taken on them.

### Report of the President

President Freedman reported to the Council on meetings in which he had participated since the February 8 meeting. He mentioned attending a meeting requested by the Connecticut Labor Council to discuss problems of mutual interest. Drs. Canzonetti, Kamens and James also were present as was Tim Norbeck. Dr. Freedman discussed the recent newspaper article about Blue Cross and Blue Shield's "black book" which lists the different charges by state physicians for hundreds of medical procedures and mentioned that he had answered a few questions from a reporter representing the Hartford Courant.

The President reported on his recent participation on a CME panel at the AMA National Leadership Conference in Chicago and stated that the CSMS survey of its members on the subject of CME has stimulated national interest.

### Report—Subcommittee on Preliminary Study of Nominations

With several amendments, it was VOTED to approve the report of the Subcommittee and to transmit a complete slate of nominees to the House of Delegates for election, with Council recommendation for approval.

### Annual Reports of Committees, Representatives and Advisors, 1978-1979

Being advised by staff that none of the subject reports made recommendation for action by the HOD, it was VOTED to transfer all annual reports to the House of Delegates.

### Department of Social Services (Department of Income and Maintenance)

After lengthy discussion of the problems involved in the Medicaid Program it was VOTED to have a committee of the Council (Drs. Freedman, Friedberg, Ragland, Sadowski and Zlotsky together with Dr. Polivy) meet with Commissioner Maher and Stephen Press to discuss possible solutions. Among the items to be discussed will be the adverse publicity received by physicians who see a large volume of welfare patients, social problems versus medical problems, disproportionate reimbursements to hospital emergency rooms versus physicians' offices, and other appropriate subjects which relate to the problems in the Medicaid Program.

### Committee on Maternal Morbidity and Mortality

It was VOTED to approve of CSMS participation, through the Committee to Study Perinatal Morbidity and Mortality, in the in-depth perinatal review (Improved Pregnancy Outcome) as proposed by the State Department of Health Services, in order to identify the problems and improve perinatal care in Connecticut.

It was further VOTED to approve of the Committee participating in the development of standards of perinatal care based on such reviews for the benefit of improved pregnancy outcome in Connecticut.

It was further VOTED to request the Committee to provide supporting data to the statement made that this state has declined in national ranking in infant morbidity and mortality rates.

A motion to take no action on a statement relating to fetal monitoring was tabled until the next meeting of the Council.

### Miscellaneous Business

Dr. Louis Backhus discussed a letter which he recently received from Dr. David M. Lowell relating to specialty representation in the CSMS House of Delegates. Mr. Norbeck was asked to respond to Dr. Lowell, pointing out that such an action would require a change in the private charter granted the Society by the Connecticut General Assembly.

Mr. Norbeck mentioned to the Council that the AMA was interested in the Society's reaction to Dr. John Barrasso's candidacy as the resident member of the AMA Council on Constitution and Bylaws. It was VOTED to endorse the candidacy of Dr. Barrasso for the resident position on the AMA Council on Constitution and Bylaws.

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on March 28, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

# In Memoriam

**CARELLI, GENESIS F.,** Yale Medical School, 1911. Dr. Carelli was a noted ophthalmologist in the New Haven area for over 52 years. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. He was also a past president of the New Haven County Medical Association and a member of the International College of Surgeons and was a member of the medical staff at both St. Raphael's and Yale-New Haven Hospitals. At the time of his death, he was physician emeritus of general surgery (ophthalmology) at these hospitals. Dr. Carelli died March 29, 1979, at the age of 89.

**KNIGHT, HAROLD F.,** University of Rochester Medical School, 1949. He joined the medical staff at St. Francis Hospital in 1957 and was director of the surgical division of the cardiovascular thoracic section. Dr. Knight served in the Army during World War II and in the Air Force during the Korean conflict. He was a member of the Hartford County Medical Society, the Connecticut State Medical Society and the American Medical Association.

**LICHT, SIDNEY,** New York University Medical School, 1931. Dr. Licht was a pioneer in the field of physical medicine. He was a Major in the U.S. Army during World War II; he was also a member of the faculty of Yale University School of Medicine and curator of the physical medical collection of Yale Medical College. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Licht died March 18, 1979, at the age of 71.

**REM, EDWARD A.,** Downstate Medical School, 1947. Dr. Rem was a general practitioner in the Fairfield area since 1947. He was a past president of the Norwalk Medical Society and of the Fairfield County Medical Society and a member of the Connecticut State Medical Society and the American Medical Association, and was the medical director for the Richardson Merrell Corp. of Wilton at the time of his death. Dr. Rem died March 12, 1979, at the age of 66.

**RYAN, V. GERARD,** Yale University, 1934. Dr. Ryan was a psychiatrist in the Middlesex area since 1941, and was a former medical director of Elmcrest Manor Hospital in Portland from 1942 to 1971. He maintained a private practice in Middletown until his retirement in 1978. During World War II he was a surgeon in the U.S. Public Health Service, and for several years was an assistant in psychiatry at Harvard Medical School. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Ryan died February 20, 1979, at the age of 68.

# PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

## OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

### ALLERGY

Physician to take over well established practice in western CT. Retiring MD will be pleased to stay on and introduce to patients. Please send resume to CSMS.

### EMERGENCY ROOM

Full time position available at modern 225-bed community hospital in eastern CT; 33,000 visits yearly; 42-hour work week; salary competitive. Send CV to G.L. Springer, M.D., Chief of Emergency Room Services, William W. Backus Hospital, 326 Washington St., Norwich, CT 06360.

### FAMILY PRACTICE

Three man Family Practice group in eastern CT shoreline looking for fourth man. Family Practice and industrial. Salary first year, partnership thereafter. Mostly office practice. Send resume to CSMS.

### PSYCHIATRY

**Residents in Psychiatry:** First, Second, Third and PGY1 year residency positions available. AMA approved program affiliated with Yale. Intensive clinical experience with outpatients and hospitalized individuals. Seminars and clinical case conferences. Training in special psychiatric problems of children, adolescents, the aged and substance abusers available; individualized track assignments for third year residents. Liberal stipends and full fringe benefits, housing at minimal cost. Connecticut Valley Hospital, Box 351, Middletown, CT 06457.

Part or full-time position for psychiatrist in specialized substance abuse facility. In-patient and out-patient services. Methadone Maintenance Program. Duties include service as Unit Chief, member of team of psychiatrists and physicians, evaluations and supervision of clinical staff. Contact: Administrator, Blue Hills Hospital, 51 Coventry St., Hartford, CT 06112 (203) 566-4405.

Psychiatrists and Physicians to work in specialized programs—drug dependence, alcoholism, geriatric rehabilitation, and general psychiatry. Setting is dynamic, decentralized and community oriented. Training affiliation with Yale. Opportunity for private practice or consultation. Elig. for CT licensure required. Salary commensurate with experience and training. Liberal benefits. Send all particulars in first letter including references to: Mehadin K. Arafeh, M.D., Supt., Connecticut Valley Hospital, Box 351, Middletown, CT 06457. EOE.

## PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

### ALLERGY

July '79. Age 32. FLEX. Am. Bds., cert.-ped. MD: India. Int., res. and fellowship: Long Island College Hosp. Wishes assoc. type practice in med. community. Contact CSMS-Allergy/YKR.

### ANESTHESIOLOGY

Available now. Age 29. MD, int., and res.: Iraq. Wishes grp., assoc. or institutional practice in CT. Adnan Alduliami, M.D., 7 Williams Blvd., Lake Grove, NY 11755.

July '79. Age 29. AB-elig. MD: India. Int. and res.: Monmouth Med. Ctr. Also res.: Bronx Lebanon Med. Ctr., NY. Solo or grp. practice desired, in med. or small community. Raveendra Limaye, M.D., 335-D Third Ave., Long Branch, NJ 07740.

July '79. Age 30. AB-elig. MD: India. Int.: Muhlenberg Hosp., NJ. Res.: Albert Einstein, NY. Presently working at Einstein as attending anes. and instructor. Jitendra G. Patel, M.D., 133-52 Avery Ave., Flushing, NY 11355.

### INTERNAL MEDICINE

**Gastroenterology:** July '79. Age. 30. Nat'l. bds., elig. MD: Emory. Int. and res.: Charity Hosp.-Tulane. Fellowship: Westchester Med. Ctr., NY. Solo, grp. or assoc. practice in Southwestern CT within 1 hr. of commuting distance of NY. Bennett H. Bruckner, M.D., 192 Garth Rd., Apt. 6M, Scarsdale, NY 10583.

**Cardiology:** July '79. Age 31. AB-elig. MD: India. Int., res. and fellowship: Catholic Med. Ctr., Queens Gen. Hosp. Will consider all types of practice in a large or med. community. K.A. Desai, M.D., 108-18 63rd Rd., Forest Hills, NY 11375.

July '79. Age 29. Conn. license. Nat'l. bds., elig. MD: UConn. Int. and res.: St. Francis Hosp., Hartford, CT. Grp., assoc. or institutional practice desired. Eva L. Morgenstern, M.D., 63 Clover Dr., West Hartford, CT 06110.

**Oncology:** July '79. Age 28. Nat'l. bds., elig. MD: P&S. Int., res. and fellowship: John Hopkins. Wishes grp. or assoc. practice in large or med. community. Contact CSMS-IM/ONCOLOGY/JSF.

**Cardiology:** July '79. Age 32. AB-elig. MD: Pakistan. Int.: Brooklyn-Jewish Hosp. Res.: Doctors Hosp., D.C. Fellowship: Deborah Hosp., NJ. Wishes solo, grp. or assoc. practice in CT. Javed Masoud, M.D., Deborah Heart and Lung Center, Browns-Hill, NJ 08015.

**Rheumatology/Immunology:** July '79. Age 30. Nat'l. bds., cert. MD and fellowship: Tufts. Int. and res.: St. Elizabeth's Hosp., Mass. Wishes grp. or assoc. practice in large or med. community. Alan B. Fishman, M.D., 70 Centre St., Brookline, Mass. 02146.

July '79. Age 31. Nat'l. bds., elig./7/79. MD: Temple. Int. and res.: SUNY. Wishes grp. practice in CT. James M. O'Malley, M.D., 142 7th North St., Syracuse, NY 13208.

**Cardiology:** July '79. Age 33. Nat'l. bds., cert. MD: India. Int.: Cook Cty. Hosp., IL. Res. and first yr. fellowship: Kings Brook Jewish Med. Ctr., NY. Second and third yr. fellowship: St. Univ. of NY at Stony Brook, VA Hosp. Solo or grp. practice desired in med. community in CT. Soma N. Pulipati, M.D., 725 E. Main St., Kings Park, NY 11754.

**Infectious Diseases:** July '79. Age 32. Nat'l. bds., cert. MD: NY Med. Coll. Int. and res.: Metropolitan Hosp. Fellowship: NY Univ. Interested in gen. IM with opportunity to practice subspecialty. Wishes grp. or assoc. practice in large or med. community. Alan J. Stein, M.D., 105 W. 13th St., Apt. 15C, New York, NY 10011.

# Newly Recognized Infectious Diseases

## NEIL H. OLSON, M.D. AND RICHARD QUINTILIANI, M.D.

In this paper I will discuss briefly several infectious diseases with which we have recently become familiar. I have labelled these "newly recognized" instead of "new" because it is doubtful that any infectious disease is truly new but just that our level of clinical or laboratory sophistication reaches a point sufficient to recognize it. A couple of these diseases have not been proven to be infectious, but the weight of epidemiologic evidence is in favor of that conclusion.

The first disease I'd like to discuss is Legionnaires' disease. So much has been written about this recently that I risk overdosing the reader. However, there is need for a clinically-oriented capsule summary of this disease.

It is a pneumonia predominantly in patients over the age of 40 (75% are 40-69 years old),[1] frequently with underlying organ system disease which presents similarly to viral or mycoplasma pneumonia with anorexia, malaise, headache, myalgia, and dry cough. Pleuritic chest pain is frequent, and dyspnea and G.I. symptoms (diarrhea and vomiting) also occur commonly. Obtundation occurs in about 20% of patients. Within a day of onset, the temperature rapidly rises to 102-105°F., commonly with rigors which persist intermittently until appropriate therapy is instituted. The cough gradually becomes productive over several days without frank purulence. Chest exam shows rales initially, and chest x-ray reveals a patchy infiltrate. The WBC is usually 10-24 thousand, but leukopenia has been described. Over one to several days, physical signs and x-ray evidence of consolidation develop. Pneumonia is unilateral in 50% of the patients. Only minimal effusions occur, and there is no cavitation (there is a recent report of cavitation in a severely compromised host). Other organ system involvement is manifested by abnormal urinalysis—hematuria and/or proteinuria (renal failure occurred in four of the Philadelphia cases)—and abnormal liver tests—transaminases, alkaline phosphatase, and bilirubin about 2-3 times normal.[1 2] A milder form of the disease without pneumonia has been recognized (Pontiac fever).

When a patient is first seen, mycoplasma pneumonia is unlikely because it is usually a mild illness of the under-40 age group, and because pleuritic pain and multi-system involvement are unusual. The main differential diagnostic consideration is secondary bacterial infection in a patient with viral pneumonia. Because of this and because the sputum is unhelpful in diagnosing Legionnaires' disease (in other than the research laboratory), empiric therapy may be necessary with erythromycin plus either a cephalosporin or chloramphenicol. This combination would cover the Legionnaires' disease bacillus (L.D.B.) as well as the usual common bacterial causes of pneumonia.

Recently, Legionnaires' disease (L.D.) has been found as a nosocomial infection within hospitals,[2] and thus, this diagnosis has to be considered in the patient with a hospital-acquired pneumonia.

Early in infection, the "tip off" should be the multi-organ system involvement, when present.

Erythromycin is the drug of choice, based on the fact that this drug produced the best results of the many antibiotics tried in this disease.[1 2] It yields prompt defervescene of fever and improvement in symptoms usually within 36 hours of initiation of therapy. Oral therapy appears to be as effective as I.V. therapy.[2] Rifampin is the most active drug vs. the L.D.B. in vitro,[3 4] but experience with this drug is limited in L.D., and other organisms have been known to develop rapid resistance to this drug.[5] Tetracyclines have also been effective in the majority of cases when used,[1 2] and fair *in vitro* sensitivity has been demonstrated.[3 4]

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Reprint requests to Infectious Disease Division, Department of Medicine, Hartford Hospital, 80 Seymour St., Hartford, CT 06115 (Dr. Quintiliani).

The L.D.B. (now designated *Legionella pneumophila)*[6] is a gram-negative, long filamentous rod which stains poorly with Gram's stain. It is similar in appearance to fusobacteria which are part of the normal oropharyngeal flora. The best readily available culture medium for isolation of the organism is Mueller-Hinton agar with 5% peptic digest of blood.[2] The Center for Disease Control is now trying to develop better culture media. The organism has been cultured from lung tissue and pleural fluid but not from blood or sputum. There is a fluorescent antibody test (not generally available) which can be applied to tissue and more recently has been used with success on sputum obtained by transtracheal aspirate.[7] L.D.B. can also be demonstrated in tissue using Dieterle's silver impregnation stain.[8] Serological testing is the commonest confirmatory test and is available through state health laboratories. Seroconversion is diagnostic and is defined as a 4-fold (2 dilution) or greater rise in antibody against *Legionella pneumophila* with highest titer at least 1/64 (CDC) (Finegold, 1/128).[1] [2] Seropositivity is diagnostic if it is present in a patient with a recent illness compatible with L.D. It is defined as a single titer of 1/128 (CDC), (Finegold's criteria: 1/512).[1] [2] Different strains of *Legionella pneumophila* have been discerned by serological testing.[9] Most serologies will turn positive within 3-4 weeks, but seroconversion may take as long as 6 weeks.[2]

The usual habitat of *Legionella pneumophila* is not known. It has been cultured from the water reservoirs of air conditioning systems atop buildings (Atlanta, Ga.; Memphis, Tn.; student union Bloomington, Indiana) and in one instance from a creek nearby an outbreak of disease (Bloomington, Indiana).[10] The illness is not thought to be transmissible from person to person.

To put this illness into perspective, it has been estimated that L.D. accounts for approximately 1-2 percent of all pneumonias. However, this is purely a guess and longitudinal serologic testing will be required to give better incidence data.

The next illness I'd like to discuss is Lyme arthritis (L.A.). Although this is not definitely an infectious disease, the epidemiology and behavior of the illness point strongly to this conclusion. Study of this disease began when in November 1975 two mothers from Old Lyme, Connecticut, reported to the State Health Department about an apparent clustering in their community of what had been diagnosed as juvenile rheumatoid arthritis.[11] [12] The occurrence of this illness in adults and children within the same families and in several families living near each other raised the question of an environmental agent. Subsequent retrospective and prospective analysis of cases by the CDC, Connecticut State Laboratory and Yale Division of Rheumatology demonstrated that this is a "new" disease. Its main manifestation is a nondeforming asymmetric oligo- or mono-articular arthritis (affecting mostly large joints) which is typically marked by exacerbation and remissions and classically occurs 0.6 to 22 weeks (median 4) following an enlarging erythematous skin lesion which is thought to be Erythemia Chronicum Migrans (ECM).[11] [12] This disease occurs in both children and adults.

ECM has been known for decades in Europe, especially Scandinavia, and has been thought to be transmitted by the sheep tick *Ixodes ricinus* but has also been reported in association with mosquito bites in areas without ticks[11] [12] (but unproven). [Interestingly, a small number (~13%) of the Lyme arthritis patients with ECM recalled a tick bite at the site of the subsequent skin lesion 4-20 days prior to onset of ECM. This, the presumed association in Europe of ECM with tick bites, the occurrence of Lyme arthritis in heavily wooded countryside, its summer predominance, and the fact that its epidemiology suggests an infectious etiology all point strongly to this being an arthropod-borne disease.] ECM, which may have single or multiple lesions, begins with an initial lesion on a proximal extremity or trunk (thigh; buttock, and axilla most common) consisting of a red macule or papule that gradually increases in size to a large annular lesion (6-52 cm) frequently with central clearing and/or induration and hot to touch. Multiple lesions may begin within a few days. They can last a few days to 8 weeks (median 3 weeks) and heal without residue. The skin lesions were infrequently pruritic or painful. The majority of patients with skin lesions complain of malaise, fatigue, chills, fever (100-102.9° F), headache and stiff neck, which may even precede the skin lesion(s) by a few days. The malaise and fatigue often remain for a few weeks (median 4, range 0.3 to 24) although the other symptoms usually abate within a few days. Other less frequent symptoms include backache, myalgias, nausea, vomiting and sore throat. Individual cases have had regional or generalized adenopathy, splenomegaly, malar rash or periorbital edema. Cryoglobulinemia (usually IgM) and increased serum IgM levels are frequently seen in patients with ECM (when part of the L.A. syndrome) and the vast majority of patients with these laboratory features have subsequently gone on to develop the arthritis component of the disease.

As mentioned previously, the joint symptoms begin a median of 4 weeks (0.6-22 weeks) after ECM (ECM did not always occur, however). Late summer and early fall is the peak period for initial attacks of the arthritis component. It begins usually in one or a few joints and remains mono- or oligo-articular in the majority. However, some patients complain of migratory joint pains (one at a time) in as many as 10 joints. The most commonly involved joints are the knee, often large joints, the temporomandibular joint, and occasionally the small joints of the fingers and toes, in descending order of frequency. The median duration of arthritis is 8 days but may last as long as 3 months. Recurrences (1-6) are common with periods of remission lasting 1-10 weeks. Affected knees are typically hot and quite swollen but not red. Ruptured Baker's cysts have occurred in a small number of patients. Swelling is uncommon in other joints with pain on motion frequently being the only sign of inflammation. Associated symptoms are the same as mentioned before for the initial ECM. Laboratory findings of note during attacks of arthritis consist of elevated ESR, cryoglobulinemia (IgM alone or predominantly), elevated serum IgM and abnormal joint fluid as follows: increased joint leukocytes (21,000-72,000) predominantly granulocytes, and normal complement. Synovial biopsy shows synovial hypertrophy, vascular proliferation and heavy infiltration of mononuclear cells (indistinguishable from RA).

Other organ systems may be involved. With nervous system involvement, Bell's palsy, peripheral neuropathy, aseptic meningitis or lymphocytic CSF pleocytosis alone may be seen; with cardiovascular involvement, myocardial conduction abnormalities (1st-degree block, Wenckeback, 3rd-degree block, alternating left and right bundle branch blocks) are seen.

A variety of cultural and serological tests have been done in an attempt to determine an infectious etiology without success, including the following: joint fluid cultures for bacteria, including streptobacillis moniliformis; absence of cytopathic effect of specimens on a variety of cell culture media; acute and convalescent titers vs. adenovirus, coxsackie virus A9 and B1-5, CMV, hepatitis B antigen, herpes simplex, influenza A and B, lymphocytic choriomeningitis, mumps, rubella, Mycoplasma pneumoniae, and 4 representative rickettsiae; and single sera vs. 216 arboviruses, spiroplasma (SMCA), and Babesia microti.

About ⅔ of patients have had at least one recurrence within 2-3 years after onset. The trend in most is to less painful and less frequent arthralgias with time. Although the vast majority of cases have occurred in Old Lyme, Lyme, and East Haddam, Connecticut, a few cases have come from Massachusetts, Rhode Island, Long Island and other areas of Connecticut (although a recent case was reported from Wisconsin). There is no known effective therapy. Aspirin gives only limited relief of joint symptoms as do intraanticular steroids. Systemic steroids were of some benefit to patients with neurologic or cardiac involvement.

The epidemiology suggests that this is an arthropod-borne infectious disease initially with subsequent manifestations due to immune mechanisms as suggested by the presence of cryoglobulins in the serum.

Another relatively recently described illness is Kawasaki disease (mucocutaneous lymph node syndrome, MCLS, MLNS). An infectious etiology for this disease has also not been proven. It was first reported in Japan by Dr. Tomisaka Kawasaki in 1967[13] and subsequent epidemiologic surveillance in Japan has turned up more than 10,000 cases.[14]

The syndrome was independently recognized by Melish and co-workers in Hawaii in 1971 before learning of the Japanese literature.[13]

Subsequently, over a hundred cases have been confirmed in the USA and the disease has been recognized in many other countries.[13]

It is seen almost solely in prepubertal children with a peak incidence within the first 18 months of life (in Japan) and a male-to-female ratio of 1:5.[13] In the U.S.A. the disease has been reported from 31 states, Puerto Rico and Washington, D.C. There has been no clear seasonal (slightly higher incidence in warmer months in Japan) or geographic predominance. The male/female ratio has been the same as in Japan, with 57% of patients being white, 18% black, and 25% oriental. The median age has been 3.8 years (range from 3 months to 13 years.)[13] Criteria for the diagnosis of MCLS have been set up by the Japanese MCLS Research Committee and consist of the six following criteria of which five must be met: "1) fever for five or more days and unresponsive to antibiotics; 2) bilateral congestion of ocular conjunctivae; 3) changes in the lips and oral mucosa, including dry, red fissuring "strawberry tongue," and diffuse reddening of the oropharyngeal mucosa; 4) changes in the peripheral extremities, including reddening of the palms and soles (early stage), indurative edema (early stage), and membranous desquamation, often periungual (later stage); 5) polymorphous nonvesicular truncal exanthum; and 6) acute nonsuppurative enlargement of the cervical lymph nodes."[13] Obviously, other diseases which can present similarly must be ruled out, e.g. scarlet fever.

Thrombocytosis (from 500,000 to 2 million/mm$^3$) and elevated WBC and ESR are usual. Other manifestations include meningitis, arthralgias, arthritis, diarrhea, proteinuria, sterile pyuria, and elevated liver enzymes.[14] The mortality is 1.7% in Japan (too early to determine in U.S.A.). Eighty percent of the Japanese fatalities have been in males, with male infants at special risk.[13] The most frequent cause of death is cardiac involvement, either myocardial infarction from diseased coronary arteries or heart failure or arrhythmias from myocarditis.[13] [14] Infantile periarteritis nodosa is now thought to be an especially severe form of MCLS occurring in the first few months of life, and it is often fatal.[13] [14]

Serological and cultural data have failed to implicate any infectious agent. Three independent laboratories have reported organisms in tissue (spleen, buffy coat and lymph nodes respectively) morphologically similar to rickettsiae, but further supportive evidence is lacking.[13] [14]

Study of the infectious causes of diarrhea has flourished in recent years, frequently via analysis of outbreaks of disease and because of certain technical advances (e.g. improved culture techniques and immune electron microscopy). Four organisms come to mind in this regard: *Yersinia enterocolitica, Campylobacter fetus s.s.* (subspecies) *jejuni,* rotavirus, and the Norwalk agent. The first of these, *Yersinia* (formerly Pasteurella) *enterocolitica,* was linked to gastrointestinal disease in 1939, but it has only been in the past decade that reports of this disease have greatly increased in numbers and that the importance of this organism as a pathogen has been recognized.[15] Its previous infrequent recognition relates most likely to its unusual cultural characteristics. *Y. enterocolitica* produces an enteritis which is very similar to that caused by the other well-known bacterial intestinal pathogens—salmonella, shigella and invasive E. coli. Diarrhea, which can be severe and often bloody, and fever of 102°F or greater are the most common manifestations. It is usually a self-limited illness, but the organism can invade the mesenteric lymph nodes producing mesenteric lymphadenitis, clinically indistinguishable from acute appendicitis. As many as 5% of appendectomies were performed for yersinial pseudoappendicitis in one recent Scandinavian study. Arthritis or erythema nodosum may follow yersinial infection, almost all reported from Europe. The arthritis, reactive in nature, typically occurs days to weeks after infection, presenting as a polyarthritis of the knees, ankles and fingers, and lasting from one to four months. It may occasionally become chronic, mimicking seronegative rheumatoid arthritis and is more common in HLA-B27+ individuals. The erythema nodosum is also self-limited. Yersinia infection can be life-threatening in neonates and the compromised host, leading to septicemia and hepatosplenic abscess and is fatal in 50% of the cases. Antibiotics do not appear to shorten the diarrheal form of the disease and may actually lengthen it, as is the case with salmonella enteritis. The life-threatening disease can be treated with chloramphenicol or an aminoclygoside. Trimethoprim/sulfamethoxazole may be useful, based on excellent *in vitro* activity.

Definitive diagnosis requires culturing of the organism from a stool sample (or from blood in life-threatening disease). Since *Y. enterocolitica* grows only slowly on conventional media and there is no selective medium, its colonies are obscured by the normal fecal flora. The best way to demonstrate the organism is via "cold enrichment," in which the culture is kept at 4°C for at least a week. During this time, other organisms die off and the yersinia continue to grow. Subsequent subcultures will demonstrate the organism. However, as long as three weeks of cold enrichment may be needed, and the one to three weeks of culturing usually makes this a retrospective diagnosis. Culturing at room temperature can also be done; and if yersinia is suspected, it may be found but this technique is less reliable. There is a serological test, but the large number of serotypes and false positive and negative reactions make it useful for epidemiologic studies only.

Other laboratory tests which suggest bacterial enteritis are a WBC usually over 15,000 with a left shift, and the presence of leukocytes and red cells in the stool.

The incidence of yersinial enteritis is not known. Its incidence peaks (unlike most bacterial enteritides) in the winter. It is spread by contaminated food and water and probably via animal-to-human or person-to-person transmission (by fecal-oral route). About one in a thousand infected patients may become a carrier for an unknown length of time. The organism has been recovered from deer, Canadian geese, oysters, dogs and pigs, but their role as a reservoir of disease is unknown.

The other bacterial cause of gastroenteritis which has attracted recent attention is *Campylobacter* (formerly *Vibrio) fetus subspecies* (s.s.) *jejuni.* Although only 111 cases had been documented worldwide[16] (until a recent outbreak in Vermont), prevalence studies in Europe have shown *C. fetus s.s. jejuni* (CFSJ) to be present in between 5[17] and 7%[18] of patients with diarrhea, with the incidence being highest in young children. The illness is an acute gastroenteritis with diarrhea, often slight but sometimes watery or bloody, occasionally with vomiting, and frequently with significant abdominal pain. Fever may occur.[16] As with other similar illnesses, the diarrhea is self-limiting in the majority of instances, and even though the organism is sensitive to furazolidone and erythromycin, the need for antibiotic therapy has not been determined.[16] Bacteremia can occur, especially in the compromised host; if this occurs the treatment of choice is gentamicin.

The organism is acquired by ingestion. Although person-to-person transmission occurs, animals are thought to be a potential source with some human infections being traced to contact with poultry and to young dogs with diarrhea. Isolation of the organism from the blood, if present, is no problem. However, isolation of the organism from stool has been difficult until recent years because of overgrowth by coliform organisms. There are two newer techniques for isolation of CFSJ: one involves use of a millipore filter, and the other uses media made selective by the addition of antibiotics.[16] The recent waterborne outbreak of this disease in Bennington, VT, involving about 2,000 cases emphasizes the emerging importance of this illness.[19]

Two viruses have been demonstrated in recent years to be major causes of gastrointestinal disease. This was made possible by the development of a new technique called immune electron microscopy whereby viral particles are concentrated in ultra-centrifuged fecal samples by using antibody, and then electron microscopy is performed. One of these viruses, the "Norwalk agent," is a major cause of "winter vomiting disease," which consists of epidemics of diarrhea and vomiting during the colder months (September to March) in both children and adults.[20]

The other important virus, rotavirus, is the major cause of diarrhea in infants and young children throughout the world, accounting for about half of the cases of diarrhea in this age group.[21] Fever and/or vomiting may or may not accompany the diarrhea in this illness. Both of these illnesses are usually mild and self-limiting, but death due to dehydration can occur in severe cases of rotavirus enteritis.

In conclusion, I have tried in a relatively short presentation to give an overview of some of the "newest" infectious (or presumed infectious) diseases. Appended is a short bibliography for further reading on these topics.

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# Prophylactic Antibiotics in Prosthetic Implant Surgery

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**ABSTRACT—Prophylaxis has been common practice in orthopedic and cardiovascular prosthetic surgery because of the seriousness of infectious complications. The importance of properly timed dosing and tissue penetration is emphasized in this article. At the present time cephalosporins or vancomycin are the drugs of choice for prophylaxis in implant surgery.**

## Introduction

The implantation of orthopedic or cardiovascular prosthetic devices requires major and complex surgery. These procedures have been associated with a low, but significant post-operative infection rate. The organisms usually involved are S. epidermidis and S. aureus. These organisms are normal inhabitants of the skin, and are introduced at the time of surgery. Superficial wound infections following surgery present no real problem, but an infection involving the prosthetic device is a serious complication.

Antibiotics are generally ineffective in eliminating infection from a prosthetic device, and surgical removal of the infected prosthesis is usually required to eradicate the infection. Because infection of a prosthesis is such a dreaded complication, antimicrobial prophylaxis has become accepted surgical practice in an attempt to reduce the infection rate.

## Problems in Prophylaxis

Infection occurs during the time of surgery, and this has been termed the "vulnerable period" by Burke.[1] Clearly, for any prophylactic regimen to be effective protection must be provided during the "vulnerable period." To be effective, the prophylactic antibiotic must be effective against the presumed pathogens and be present in adequate tissue concentrations for the duration of the procedure. If inadequate levels are present in the target tissue (bone or heart), then prophylaxis cannot be expected to be effective. Once intra-operative colonization of the implant has occurred, the problem becomes one of therapeutics rather than prophylaxis. Only recently has there been an appreciation of the importance of timing and tissue levels in determining the efficacy of prophylaxis in implant surgery.

Review of the literature reveals conflicting results with regard to efficacy of prophylaxis in orthopedic and cardiovascular surgery. It is difficult to compare studies that have employed different dosing and drug regimens.[2] [3] However, it is clear that until recently most studies have not taken into account the critical importance of timing and tissue penetration. Recent, well performed studies do show that prophylactic antibiotics administered appropriately with respect to dose and timing are effective in reducing septic complications of implanted devices.[4] [5]

## The Choice of Antibiotics

The antibiotic selected for prosthetic prophylaxis should be active against both S. epidermidis and S. aureus. Although the semi-synthetic penicillins (oxacillin, methacillin and nafcillin) and clindamycin have been successfully used prophylactically, they are not the preferred antibiotics in implant surgery. Semi-synthetic penicillins and clindamycin possess excellent anti-S. aureus activity, but are ineffective against many strains of the more common pathogen, S. epidermidis.[6] In contradistinction, the cephalosporins are consistently active against virtually all strains of both S. epidermidis and S. aureus (Table 1).

Vancomycin offers great promise as a prophylactic antibiotic in orthopedic and cardiovascular surgery because of its potent anti-Staphylococcal activity. Less toxic than previously thought, vancomycin is

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Table 1

ANTI-STAPHYLOCOCCAL ACTIVITY OF PROPHYLACTIC ANTIBIOTICS

| *Antibiotic* | *% Susceptibility* | |
|---|---|---|
| | *S. Aureus* | *S. Epidermidis* |
| Semi-synthetic Penicillins | 99% | 80% |
| Clindamycin | 95% | 85% |
| Cephalosporins | 99% | 99% |
| Vancomycin | 100% | 100% |

rapidly emerging as the best anti-Staphylococcal drug available at the present time. Prophylactically, vancomycin has been used with success to reduce the incidence of shunt (implant) infections in patients undergoing chronic hemodialysis.[7] Because the drug is not removed by dialysis and the t ½ is greatly increased in patients with end-stage renal diseases, a single dose can provide adequate serum levels up to one month.[8] At the present time, experience with vancomycin as in a prophylactic implant is limited, but vancomycin may well become the agent of choice in the near future.

### Timing

To achieve adequate tissue concentrations for the duration of the procedure, the antibiotic must be administered at the proper time before surgery. Most studies concerned with prophylactic antibiotics have failed to take into account the critical importance of the timing even when the proper drug was selected. Traditionally, antibiotics have been administered the night before or on the morning of surgery. Prophylactic antibiotics administered in this fashion have little chance of being effective because they are not present in adequate concentration in the target tissue during the procedure. Some studies have even employed prophylactic antibiotics after the completion of the operation. Studies on the penetration characteristics of antibioties in bone and heart provide the best guide for the proper timing of antibiotics before surgery.[4 5 9 10 11]

If adequate tissue levels can be assured for the duration of the procedure, the next consideration is how long should prophylaxis be provided after the procedure. If coverage is provided during the vulnerable period and the patient has normal host defences, no additional antibiotic coverage should be necessary. However, because of the great fear of infection, surgeons have continued prophylaxis for days or weeks following the operation. Many of the complications associated with prophylaxis, particularly microbial super-infection, have resulted from unnecessarily long periods of antibiotic administration.[12 13] Optimal protection is achieved if the drug is given just prior to surgery so that adequate tissue levels are maintained for the duration of the procedure. The current trend is clearly in the direction of providing a single, properly timed, preoperative dose of an antibiotic which may or may not be supplemented by an intraoperative dose with no additional prophylaxis following surgery.

### Tissue Penetration

To be effective in the area where the prosthetic device is being implanted the antibiotic should attain peak concentration in tissue in excess of four times the minimal inhibitory concentration of the organism. In general, drugs that have short half-lives because of rapid rates of renal elimination usually produce low tissue levels. However, drugs that are highly protein-bound and that have long half-lives (t ½) usually result both in high serum and tissue levels.

Although the semi-synthetic penicillins and clindamycin penetrate bone and heart tissue well, they are not the preferred agents in implant surgery because of their relative inactivity against S. epidermidis. However, cephalosporins in addition to having the proper antimicrobial spectrum penetrate tissue very well and are the drugs of choice at the present time.[14] Cephalosporins differ markedly with respect to their penetration characteristics even in the same target tissue i.e., bone (Figure 1) and (Table 2). Therefore, the clinician should be familiar with the penetration characteristics of the drugs used in prophylaxis to be assured of adequate tissue levels for the duration of the procedure.[5 9 10 11 15 16 17]

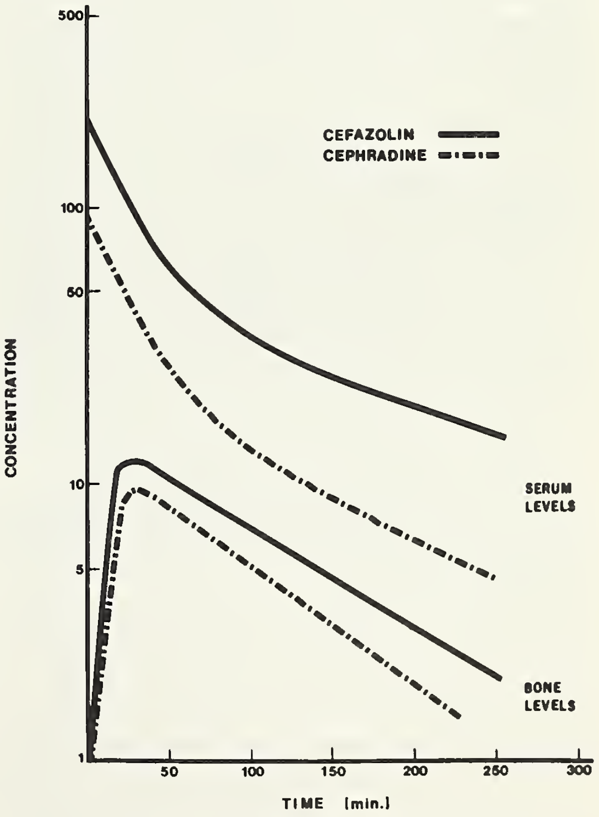

Figure 1
Serum and bone levels after 1 gm (IV) bolus injection in patients undergoing total knee arthroplasty.

Table 2

COMPARISON OF CEPHALOSPORIN PHARMACOKINETICS IN BONE

| *Antibiotic* | *Mean Peak Bone Levels (mcg/gm)* | *Time to Peak Bone Levels (min)* | *t ½ Bone (min)* | *Mean MIC Pen-R S. Aureus (mcg/ml)* | *Bone: MIC Ratio* |
|---|---|---|---|---|---|
| Total Hip Replacement | | | | | |
| Cefazolin | 30 | 40 | 42 | 0.4 | 60:1 |
| Cephradine | 23 | 20-40 | 40 | 3.4 | 7:1 |
| Total Knee Replacement | | | | | |
| Cefazolin | 15 | 30 | 85 | 0.4 | 30:1 |
| Cephradine | 9.5 | 30 | 67 | 3.4 | 3:1 |

## Practical Approach to Implant Prophylaxis

In order to be assured of adequate tissue concentration for the duration of the procedure, it is preferable to administer the antibiotic immediately before surgery. This may be done by administering the drug operatively or in the operating room itself just before the procedure. Either 1-2 gms of a cephalosporin or 1 gm of vancomycin given by intravenous injection will provide optimal protection. If the procedure is unusually long, an additional intraoperative dose (repeat initial dose) may be given to extend the period of protection.

Some surgeons prefer to continue parenteral prophylaxis for an additional 24-hour period. While this probably affords no additional advantage, it is not detrimental to the patient. Extended prophylaxis with oral medications for days or weeks following the procedure should be avoided.

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# Pharmacokinetic Considerations in the Treatment of Urinary Tract Infections

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**ABSTRACT—Urinary tract infections are the commonest infectious disease in practice and yet many drugs used in treatment are not often used to best advantage. This article emphasizes the importance of urine levels and urinary spectrum of antimicrobial therapy in selecting therapeutic agents.**

### Introduction

Pharmacokinetic principles have particular relevance in the treatment of urinary tract infections because of the renal concentration of antibiotics in the urine. Antibiotic concentrations in the urine are usually greatly in excess of achievable serum levels and antibiotics may have an expanded spectrum at urinary concentrations. The normally acid pH of the urine also changes the activity of many drugs against various organisms. Furthermore, the urine pH can be pharmacologically manipulated to therapeutic advantage in the treatment of urinary tract infections (UTI's). Clinicians treating UTI's should be aware of urinary spectrum of antibiotics at different pH levels.

Although urinary spectrum and pH manipulation are important factors in antibiotic selection, others merit consideration. Therapeutic effectiveness, resistance potential, and adverse reaction rate are the most important factors in selecting an antibiotic.

### Urine Concentration of Antibiotics

Many antibiotics are concentrated by the kidney to very high concentrations in the urine. Penicillin is a prime example of an antibiotic that is concentrated well in the urinary tract when administered by the oral route. Given orally, 500 mg of Penicillin G will produce concentrations in the serum of only 0.5 mcg/ml, but in the urine produces concentrations of 100 mcg/ml. The minimal inhibitory concentration (MIC) of most *E. coli, P. mirabilis,* and *Enterococci* are less than 60 mcg/ml. Therefore, penicillin has been found useful in treating urinary tract infections because of its high concentration in the urine, well above the MIC of susceptible organisms.[1] Urinary isolates of *E. coli, P. mirabilis,* and the *Enterococcus* are reported as insensitive to penicillin by standard disc sensitivity testing.. This occurs because sensitivity disc testing is applicable only to concentrations of drug achievable in the serum with ordinary dosing by the Kirby-Bauer method.[2] Since routine disc sensitivity is relevant only in serum levels, the clinician should be familiar with the urinary spectrum of the drug since this is not included in the laboratory report.

In conclusion, the urinary spectrum of common antibiotics, orally administered, is quite different from serum spectrum, and these differences should be taken into account in selecting an agent for the treatment of urinary tract infections.

### Pharmacological Alteration of Urinary pH

The manipulation of urinary pH can be a valuable adjunct in the treatment of urinary tract infections. An acidified urine is a normal host defense mechanism that assists in suppressing the growth of coliforms. Acidification of the urine by pharmacologic means enhances the inhibitory effect of the normally acid urine as well as increasing the activity of some antibiotics in the urine. Alternately, alkalinization of the urine can antagonize acid-dependent drugs as well as potentiate the effects of alkaline-dependent drugs.[3] (Tables 1, 2)

Acidification of the urine can be achieved in a variety of ways. Methionine and ammonium chloride

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Table 1

THE EFFECT OF URINARY pH ON ANTIBIOTICS

*Optimal Activity Requires Neutral Urine*

Penicillin G
Trimethoprim-Sulfamethoxazole (TMP-SMX)
Oral Cephalosporins

*Activity Not Affected By Urinary pH*

Nalidixic Acid
Oxolinic Acid
Ampicillin
Chloramphenicol

Table 2

THE EFFECT OF URINARY pH ON ANTIBIOTICS

*Activity Increased By Acid Urine*

Tetracycline
Nitrofurantoin (Concentration in Renal Lymph)

*Activity Requires An Acid Urine*

Methenamine Mandelate
Methenamine Hippurate

*Activity Increased By Alkaline Urine*

Erythromycin
Aminoglycosides
Sulfonamides
Nitrofurantoin (Concentration in Bladder)

may be used for this purpose, but ascorbic acid is inexpensive and least toxic. Urine pH must be maintained below 5.5 to significantly increase the action of acid-potentiated drugs and effectively inhibit coliforms. The quantity of acidifying agent required to maintain the urine pH at 5.5 is highly variable, and must be titrated for each individual. With ascorbic acid, 8-12 grams may be required in divided doses on a daily basis. Urinary pH should be measured every 6 hours to be sure that the desired pH is maintained throughout the day.[4] In situations where systemic acidosis would be detrimental to the patient, acidifying agents should not of course be used.

Alkalinization of the urine can be achieved by acetazolamide 500 mg. (PO) qh8 or sodium bicarbonate 1-2 grams (PO) q4h.[5] Again, as with acidifying drugs, great individual variation occurs, and only frequent monitoring of the urinary pH and individual drug titration can accomplish the desired result. Clearly, these drugs cannot be used in patients where systemic alkalosis or the additional sodium load (1 gram of $NaHCO_3$ = 13.5 mEq Na+) cannot be tolerated.

## Effect of pH on Selected Antibiotics

*Nitrofurantoin*

The concentration of nitrofurantoin in the upper or lower urinary tracts can be modified by manipulation of urinary pH. The tubular reabsorption of nitrofurantoin is promoted by an acid urine which results in concentration of the drug in renal lymph. Conversely, in the presence of an alkaline urine, tubular reabsorption is decreased resulting in the increased concentration of nitrofurantoin in the bladder.[6]

*Trimethoprim-Sulfamethoxazole (TMP-SMX)*

Some drugs require a neutral urinary pH to be effective and are less active at extremes of pH. Included in this group are penicillin G, the oral cephalosporins, and TMP-SMX. The action to TMP-SMX depends on the synergistic effect of a fixed ratio of TMP to SMX. With acidification of the urine, the renal clearance of TMP is increased and the amount of SMX is decreased in the urine, and the opposite effect is observed during alkalinization. Consequently, renal clearance rates and subsequent urinary concentrations of each component differ markedly at extremes of pH which result in a suboptimal ratio of TMP to SMX. Therefore, TMP-SMX requires a neutral urine to be maximally effective.[7]

*Erythromycin*

Alteration of antibiotic spectrum by manipulation of urine pH is most pronounced with erythromycin.[8] Standard oral doses of erythromycin are effective only against the Enterococcus at normal urinary pH. Alkalinization of urine pH to 8.0 expands the antibacterial activity of erythromycin to include not only the Enterococcus, but E. coli, Klebsiella, Enterobacter, Serratia, and most strains of Proteus and Pseudomonas.[9] This effect is thought to be the result of increased amounts of non-ionized drug available in alkalized urine.

## The Urinary Spectrum of Antibiotics

The urinary spectrum of common antibiotics orally administered is quite different from serum spectrum, and these differences should be taken into account in selecting an agent for the treatment of urinary tract infections.

*Penicillin G*

Although penicillin is acid labile, and gastric absorption is limited to 30% of the ingested dose, and renal concentration results in high urinary concentrations, penicillin has been shown to be an effective drug in uncomplicated UTI's due to susceptible strains of *E. coli, P. mirabilis,* and the *Enterococcus.* R-factor resistance has not been a problem with penicillin in the treatment of UTI's.

*Penicillin in the Treatment of UTI's*

Penicillin is capable of inducing L-forms, but this has not been a problem in the urinary tract. Since penicillin has not been associated with R-factor resistance, is well tolerated and relatively non-toxic, and achieves high concentrations in the urine, it is a useful drug in the therapy of UTI's.[10] (Table 3)

Table 3

PENICILLIN G
(Dose: 500 mg Orally)

| Serum Levels: | Urine Levels:[27] |
|---|---|
| 0.5 mcg./ml. | 100 mcg./ml. |

URINARY SPECTRUM

| Effective Against: * | Misses: |
|---|---|
| E. coli | Klebsiella-Enterobacter-Serratia |
| P. mirabilis | Pseudomonas |
| Enterococcus | Indole pos. Proteus |

**MIC's less than 60 mcg./ml.*

### Ampicillin

Five-hundred mg of ampicillin given orally results in concentrations of about 300 mcg/ml in the urine. The urinary spectrum of ampicillin includes *E. coli, P. mirabilis,* and the *Enterococcus.* Unfortunately, the usefulness of ampicillin has been greatly diminished by the widespread use of the drug which has resulted in the emergence of resistant coliforms in a large segment of the population. Because only 70% of the *E. coli* remain sensitive to ampicillin at Hartford Hospital, ampicillin can no longer be relied upon to be consistently effective against *E. coli.* Furthermore, ampicillin is a highly sensitizing drug that often results in hypersensitivity reactions, and is the commonest cause of drug fever at our institution.[11] [13] Because of ampicillin's propensity to develop resistance and hypersensitivity reactions, its continued usage should be more selective. (Table 4)

Table 4

AMPICILLIN
(Dose: 500 mg. Orally)

| Serum Levels: | Urine Levels:[28] |
|---|---|
| 2 mcg./ml. | 300 mcg./ml. |

URINARY SPECTRUM

| Effective Against: * | Misses: |
|---|---|
| E. coli | Klebsiella-Enterobacter-Serratia |
| P. mirabilis | Pseudomonas |
| Enterococcus | Indole pos. Proteus |

**MIC's less than 5 mcg./ml.*

Table 5

AMOXICILLIN
(Dose: 500 mg. Orally)

| Serum Levels: | Urine Levels:[29] |
|---|---|
| 4 mcg./ml. | 600 mcg./ml. |

URINARY SPECTRUM

| Effective Against: * | Misses: |
|---|---|
| E. coli | Klebsiella-Enterobacter-Serratia |
| P. mirabilis | Pseudomonas |
| Enterococcus | Indole pos. Proteus |

**MIC's less than 5 mcg./ml.*

### Amoxicillin

Urinary concentrations of amoxicillin are double those achievable with ampicillin, i.e., 600 mcg/ml, but these high levels do not result in a wider urinary spectrum. (Table 5) However, because amoxicillin is better tolerated than ampicillin this may be an advantage in some patients.[14] Recently, single high dose amoxicillin therapy has been found to be as effective as conventional 5-7 day therapy in uncomplicated urinary tract infections.[15]

### Indanyl carbenicillin

Carbenicillin is the only orally administered antibiotic with consistent activity against indole-positive *Proteus* and *Pseudomonas aeruginosa.* Although the oral form of the drug produces inadequate serum levels, its high concentration in the urine makes this a useful drug for the urinary tract infection due to the sensitive organisms. Because of the rapid emergence of resistant forms when used alone, carbenicillin should be reserved for the treatment of bacteriurias that cannot be controlled by other orally administered antibiotics. Since carbenicillin is a penicillin derivative, the drug should not of course be used with patients allergic to penicillin. The urinary spectrum of carbenicillin includes all of the usual gram negative coliforms except *Klebsiella* and *Serratia.*[14] (Table 6)

Table 6

INDANYL CARBENICILLIN
(Dose: 500 mg. Orally)

| Serum Levels: | Urine Levels:[30] |
|---|---|
| 10 mcg./ml. | 1000 mcg./ml. |

URINARY SPECTRUM

| Effective Against: * | Misses: |
|---|---|
| Enterobacter | Klebsiella |
| Indole pos. Proteus | Serratia |
| Pseudomonas | |
| Enterococcus | |

**MIC's less than 125 mcg./ml.*

### *Cephalosporins*

Cefalexin and cephradine are oral cephalosporins commonly used to treat urinary tract infections. Their primary usefulness is in treatment of *Klebsiella* urinary tract infections or in patients with UTI's due to susceptible organisms that are allergic to penicillin. The spectrum of cephalosporins in the urine is narrow and limited to *E. coli, P. mirabilis,* and *Klebsiella.* The Enterococcus is notably resistant to the cephalosporins.[16] [17] Oral cephalosporins are relatively expensive and are probably overused in the treatment of urinary tract infections. Cephalosporins are also likely to induce R-factor resistance in coliforms and this should be kept in mind in designing therapy for the patient. (Table 7)

Table 7

CEPHALEXIN/CEPHRADINE

(Dose: 500 mg. Orally)

| *Serum Levels:* | *Urine Levels:*[31] |
|---|---|
| 15 mcg./ml. | 1000 mcg./ml. |

URINARY SPECTRUM

| *Effective Against:* * | *Misses:* |
|---|---|
| E. coli | Enterobacter-Serratia |
| P. mirabilis | Indole pos. Proteus |
| Klebsiella | Pseudomonas |
| | Enterococcus |

**MIC's less than 100 mcg./ml.*

### *Tetracyclines*

Tetracyclines, like the penicillins, are concentrated in the urine by the kidney. Long acting tetracyclines, i.e., minocycline and doxycycline, because of their high protein binding are poorly concentrated by the kidney, limiting their usefulness in the urine. The short acting tetracyclines are present in the urine in high concentration and are active against *E. coli, Klebsiella, Enterobacter* and 100% of *Pseudomonas* strains.[18-19] With the exception of doxycycline, tetracyclines are contraindicated in renal failure. (Table 8)

Table 8

TETRACYCLINE HCl

(Dose: 500 mg. Orally)

| *Serum Levels:* | *Urine Levels:*[32] |
|---|---|
| 2 mcg./ml. | 300 mcg./ml. |

URINARY SPECTRUM

| *Effective Against:* * | *Misses:* |
|---|---|
| E. coli | P. mirabilis |
| Klebsiella | Serratia |
| Enterobacter | Enterococcus |
| Indole pos. Proteus | |
| Pseudomonas | |

**MIC's less than 150 mcg./ml.*

### *Erythromycin*

Erythromycin is a drug useful in the treatment of *Enterococcal* UTI's in patients allergic to penicillin. The spectrum of erythromycin activity in the urine is greatly enhanced by alkalinization, and this may be used to therapeutic advantage in selected situations. Hypersensitivity reactions to the drug are rare making this drug a useful alternative in patients sensitive to penicillin or sulfonamides.[11-13] Resistance has not been associated with erythromycin therapy, and it has the additional advantage of being active against L-forms produced by cell wall active drugs such as penicillin and cephalosporins.[14] [20] (Table 9)

### *Nalidixic and Oxolinic*

Oxolinic acid is a congener of nalidixic acid, but differs from it in several respects and is more active against susceptible pathogens than it, but is more toxic to the CNS. Both chromosomal and R-factor resistance has been a problem with both drugs. Recent data suggest that the administration of higher doses of these drugs may minimize the resistance problem.[3, 14] (Table 10)

Table 9

ERYTHROMYCIN

(Dose: 500 mg. Orally)

| *Serum Levels:* | *Urine Levels:*[33] |
|---|---|
| 1 mcg./ml. | 30 mcg./ml. |

URINARY SPECTRUM

| *Effective Against:* * | | *Misses:* |
|---|---|---|
| pH = 7.4 | Enterococcus | All others |
| pH = 8 | E. coli | Indole pos. Proteus |
| | P. mirabilis | Pseudomonas |
| | Enterococcus | |
| | Klebsiella | |
| | Enterobacter | |
| | Serratia | |

**MIC's less than 1.5 mgc./ml.*

Table 10

NALIDIXIC ACID / OXOLINIC ACID
(Dose: 1000 mg. Orally)

| Serum Levels: | Urine Levels:[34] |
|---|---|
| 25 mcg./ml. | 200 mcg./ml. |

URINARY SPECTRUM

| Effective Against: | Misses: |
|---|---|
| E. coli | Klebsiella-Enterobacter-Serratia |
| P. mirabilis | Indole pos. Proteus |
| | Pseudomonas |
| | Enterococcus |

*Sulfonamides*

Sulfonamides have been used for years in treating urinary tract infections. Sulfonamides act by interfering with folate synthesis and are bacteriostatic. Many preparations of sulfa drugs are available and these are best classified by their excretion rates as short, medium, or long-acting sulfonamides. The renal clearance of all sulfonamides is dependent on the urinary pH. In the urine, sulfonamides are only active against *E. coli* and *P. mirabilis*. The main disadvantage with sulfa drugs is their side effects and potential for producing resistant coliforms.[13, 14] Such widespread resistance to sulfa drugs has limited their usefulness in treating *E. coli* urinary tract infections. Furthermore, sulfa drugs are highly sensitizing compounds that often produce rashes or drug fevers.[11-13] (Tables 11, 12)

*Trimethoprim-sulfamethoxozole (TMP-SMX)*

Trimethoprim-sulfamethoxazole (TMP-SMX) when combined in a ratio of 5 (400 mg of SMX) to 1 (80 mg of TMP) are synergistic in vitro. TMP-SMX is probably the best drug currently available to treat urinary tract infections with respect to tissue penetration and antibacterial spectrum. The urinary spectrum of TMP-SMX includes *E. coli, P. mirabilis,* most of the indole-positive *Proteus, Enterobacter, Klebsiella, Serratia,* and some *enterococci.* Although as many as 20% of *Pseudomonas* strains may be sensitive to the drug, TMP-SMX is usually regarded as ineffective against *Pseudomonas aeruginosa.*[21] The combination of sulfamethoxazole with trimethaprim has resulted in the elimination of the resistance potential seen with sulfonamides when used alone.[22] The dosage of TMP-SMX should be reduced in the presence of renal failure and used with caution when the creatinine clearance is less than 10 mg/ml.[14] (Table 13)

Table 11

SULFONAMIDES

1. "Short acting" sulfonamide.
2. Half life (t½) = 3 hours (Q.I.D. dosing)
3. 30% acetylated by liver, and acetylated produce excreted in urine.
4. 70% of active drug excreted unchanged in urine.

*Sulfamenthoxazole* (Gantanol)

1. "Long acting" sulfonamide.
2. Half life (t½) = 11 hours (B.I.D. dosing)
3. *70% acetylated by liver,* and acetylated product excreted in urine.*
4. 30% of active drug excreted unchanged in urine.

**Acetylated product relatively insoluble in urine.*

Table 12

SULFONAMIDES
(Dose: 500 mg. Orally)

| Serum Levels: | Urine Levels:[35] |
|---|---|
| 40 mcg./ml. | 100 mcg./ml. |

URINARY SPECTRUM

| Effective Against: * | Misses: |
|---|---|
| E. coli | Klebsiella-Enterobacter-Serratia |
| P. mirabilis | Indole pos. Proteus |
| | Pseudomonas |
| | Enterococcus |

**MIC's less than 25 mcg./ml.*

*Nitrofurantoin*

The synthetic nitrofurans are unique among antibiotics in their ability to preferentially concentrate in the upper or lower urinary tract depending on the pH of the urine. Tubular reabsorption of nitrofurantoin is pH dependent, providing the clinician the unique opportunity of preferentially concentrating the drug in the upper or lower urinary tract by manipulating the urinary pH.[6] Hypersensitivity reactions to the drug are uncommon, but have been overemphasized in the literature.[23-24] An advantage of nitrofurantoin therapy has been the lack of development of chromosomal or R-factor resistance even after years of widespread use. The macrocrystaline form of nitrofurantoin is less irritating to the GI tract.[25] Nitrofurantoin is contraindicated in even mild renal insufficiency. Nitrofurantoin has a wide urinary spectrum that includes all gramnegative coliforms except *Proteus* and *Pseudomonas* species. Addition-

Table 13

TRIMETHOPRIM-SULFAMETHOXAZOLE (TMP-SMX)
(Dose: 1 Tablet Contains)*

*1 Tablet Contains:
80 mg. TMP (Trimethoprim)
400 mg. SMX (Sulfamethoxazole)

| *Serum Levels:* | *Urine Levels:*[36] |
|---|---|
| TMP = 2 mcg./ml. | TMP = 60 mcg./ml. |
| SMX = 40 mcg./ml. | SMX = 150 mcg./ml. |

URINARY SPECTRUM

| *Effective Against:* | *Misses:* |
|---|---|
| E. coli | Pseudomonas |
| P. mirabilis | |
| Indole pos. Proteus | |
| Klebsiella-Enterobacter-Serratia | |
| Enterococcus (50%) | |

Table 14

NITROFURANTOIN
(Dose: 100 mg. Orally)

| *Serum Levels:* | *Urine Levels:*[37] |
|---|---|
| 0 | 200 mcg./ml. |

URINARY SPECTRUM

| *Effective Against:* * | *Misses:* |
|---|---|
| E. coli | P. mirabilis |
| Klebsiella | Indole pos. Proteus |
| Enterobacter | Serratia |
| Enterococcus | Pseudomonas |

**MIC's all less than 100 mcg./ml.*

ally, nitrofurantoin is one of the few drugs available with activity against the *Enterococcus* in patients sensitive to penicillin derivatives.[14] (Table 14)

*Methenamine Salts*

Methanamine mandelate and methenamine hippurate are useful in chronic suppressive therapy where elimination of the UTI is not possible. Methenamine salts are converted to formaldehyde in the presence of an acid urine. The pH of the urine must be maintained below 5.5 for adequate conversion of methenamine to formaldehyde. Twenty percent of methenamine is hydrolyzed to form formaldehyde at pH 5, but only 6% is hydrolyzed at pH 6. Therefore, the maintenance of an acid urine, i.e., below 5.5 is essential for full activity of these salts. An additional two hours are required for the formaldehyde to reach bacteriocidal concentrations at normal bladder volumes, and an additional 6 hours are required to fully inhibit the replication of coliforms.[26] Because formaldehyde is formed only in bladder urine, methenamine salts should not be used to treat upper urinary tract infections. Because bacteria do not become resistant to formaldehyde, methenamine salts are ideal agents for chronic suppressive therapy. Alternately, nitrofurantoin or TMP-SMX are useful agents for chronic suppressive therapy because of their wide spectrum and low propensity to develop resistance with long term use. (Table 15)

Table 15

METHENAMINE HIPPURATE / MANDELATE
(Dose: 100 mg. Orally)

| *Serum Levels:* | *Urine Levels:*[38] |
|---|---|
| 0 | 1) pH dependent |
| | 2) time dependent |
| | 3) volume dependent |

URINARY SPECTRUM

| *Effective Against:* | *Misses:* |
|---|---|
| E. coli | None |
| P. mirabilis | |
| Indole pos. Proteus | |
| Klebsiella-Enterobacter-Serratia | |
| Pseudomonas | |
| Enterococcus | |

## Conclusion

The urinary spectrum of antibiotics is an important factor in the selection of an antimicrobial agent to treat urinary tract infections. The clinician should be familiar with the urinary spectrum of the commonly used antibiotics because this information is not available on the standard laboratory report. Pharmacokinetic principles are clinically important and are useful in maximizing the effectiveness of antimicrobial chemotherapy in the urinary tract.

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# The Health Care Value of Laboratory Tests

RAYMOND C. BARTLETT, M.D.

**ABSTRACT—The volume and cost of laboratory tests has increased at a rate almost double that of total hospital costs. Much of this is the result of the established attitude that no cost should be spared in the production of information that could be of *any* possible value for patient care. Evidence is presented that laboratory tests are not being utilized with maximum efficiency. Various control measures have been introduced but there is doubt that they will be effective unless current patterns of medical practice are modified to place a greater incentive on physicians for cost reduction. Evaluation and control of the quality of exudates and urine specimens were introduced in the author's laboratory. The percentage of suboptimal specimens declined from 43% to 24% between 1974 and 1976, the most striking decrease being in those specimens that were improperly submitted. An 18% reduction in the cost of processing these specimens was computed for 1974 and 9% for 1976. Evaluation and control of use of other tests will require development of more objective criteria to determine their clinical value. This may be based on precise definitions of diagnostic efficiency, but the net health care value of a test is modified by variations in laboratory and clinical costs, discomfort and morbidity. Additional qualifications result from lack of evidence that laboratory tests reduce ultimate cost, morbidity and mortality by contributing to earlier diagnosis. Costs can be reduced by controls imposed within the laboratory but maximum benefits will only be derived through prospective and retrospective quantitative assessment of alternative clinical decisions which affect the ordering of laboratory tests.**

## Introduction

In 1975 over 2 billion laboratory tests were performed in the clinical laboratories of this country. The cost was estimated at 6-12 billion dollars and may reach $48 billion per year by 1985 if the current annual 15% rate of growth continues.[1] [2] Griner and Liptzin in 1971 observed an increase in total hospital costs of 126% for the preceding five years.[3] During the same period laboratory costs increased 229%, almost double that of the increase for total hospital costs. The annual volume of all tests performed in the Department of Pathology of the Hartford Hospital doubled from 760,000 in 1967 to over 1,500,000 in 1977. This rate of growth is typical of clinical laboratories in hospitals in the United States.[3] The expanding use may be ascribed in part to established customs and attitudes that have led physicians to submit and process as many specimens as often as could be of *any* possible value for patient care: caused laboratorians to apply the most thorough, precise, and accurate available method of analysis; and promote both collection of specimens and reporting of results at more frequent intervals with decreased "turn around time."

Some might not consider this nation's expenditure on health excessive considering that it is less than 10% of income after taxes, represents only three times that spent on alcohol, six times that spent on tobacco and two-thirds that spent on automobile transportation.[4] Indeed American medicine has hoped that the increasing expense would be accepted as the justifiable cost for the best health care system in the world. But we are spending over $500 per year per capita on health and there are reports of greater longevity and lower infant mortality elsewhere.[5] [6] Almost half of total health expenditures is now reimbursed or paid directly by government. There is general recognition that all of this has provided a greater access to health services which has led to further increase in health care costs. There is great apprehension that further uncontrolled access to the system will result in

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additional uncontrolled increase in cost. There is growing public doubt that increases in the quality and availability of health service are commensurate with the rising cost. Vast inequities in the delivery of health care, including laboratory services, to various sectors of the population have continued. Variations of up to 700% in per capita application of laboratory services have been reported.[7] Thus both industry and government recognize an increasing need to place the incentive for more efficient use of health care resources on physicians who despite their role as providers also constitute the greatest consumers of these services. What evidence do we have that laboratory resources are not being efficiently used?

## Inefficient Use of Clinical Laboratories

### *Extent of Problem*

Griner and Liptzin divided patients with ketoacidosis into two groups that were comparable except for the numbers of laboratory tests which were performed. In one group 16-63% additional laboratory tests were performed but there was no apparent difference in duration of hospitalization or morbidity.[3] They doubted that the trend toward routine urine cultures irrespective of findings in urine sediment, and the practice of collecting daily sputum cultures from patients in pulmonary intensive care units were of sufficient benefit to justify their cost. They suggested that the number of urine cultures may have increased because urinalyses were performed by the house staff. They conducted a systematic attempt at the University of Rochester to inform attending physicians and house staff as well as medical students of the cost of laboratory tests by distributing patient bills and incorporating discussions of the usefulness of test performance in educational activities. During a nine-month period subsequent to introduction of this policy, no increase was observed in the number of tests which were ordered.

Skipper and his associates have drawn attention to the unfamiliarity of medical students with the cost of tests.[8] Students in the first year class were able to estimate the correct cost of tests to the nearest dollar only 8% of the time. This figure rose to 9.3% and 9.4% for the second and third year classes respectively. Only one-third of the estimates fell within 25% of the actual cost of the test. It was discouraging to these authors that knowledge of cost increased only slightly with progress through medical training.

Freeborn and his associates studied the effect of clinical experience of physicians on use of laboratory services in the Kaiser-Permanente Group.[9] More experienced physicians as well as older physicians used fewer laboratory tests than younger physicians. Board certified physicians and physicians in leadership roles used fewer laboratory tests.

A minority of writers including Bernard project that a savings would result from increasing the use of laboratory tests.[10] He felt that advances in technology and increasing discrimination provided by computers would integrate laboratory data with clinical observations to establish more rapid and accurate diagnoses. He concluded that society would also accrue savings through marked reduction in absence from work or inefficiency at work. Supporting this view, Sheeley showed that the length and cost of hospitalization were reduced through increased utilization of diagnostic and therapeutic services.[11]

Apart from the extent of utilization, the way information that is reported from the laboratory is used affects its ultimate value for patient care. Physicians often place greater confidence in clinical intuition when it conflicts with laboratory reports. Heiman observed that 50% of abnormal urinalysis findings apparently were ignored by physicians; in these cases the medical record contained no discussion of the result and no evidence of any follow-up investigation. He concluded that physicians either did not observe the reports or that they chose to dismiss the findings as insignificant.[12]

Kirby has recently drawn attention to the continued propensity of some physicians to ignore laboratory reports of antimicrobial susceptibility despite published evidence of increased analytical reliability and reduction in morbidity and mortality when therapy is guided by these results.[13] Many physicians seem to believe that results of in vitro antimicrobial susceptibility testing often correlate poorly with clinical outcome. Kirby felt that physicians should not persist in the use of an antimicrobial in a patient in whom a therapeutic trial had shown a favorable response if the laboratory had reported the organism to be resistant.

Edwards and his associates observed that changes in therapy were made only 7% of the time when cultures were reported.[14] Anderson and her associates concluded that there was no consistent logical approach to the use of serum gentamicin assays.[15] Valid indications for performance of the assays were found in 89% of instances but in one-half, specimens were improperly collected. No change in therapy occurred in 40% of instances. They concluded that only 20% of the assays resulted in appropriate therapeutic decisions. Kirby viewed the problem as an educational challenge that might require the passage of a whole generation of physicians before a more objective attitude could effectively influence the use of such data.[13]

### *Too Much Information*

Southgate recently stated, "the problem in clinical diagnosis today is no longer one of not being able to get enough information about a patient; it is the problem of being able to get too much."[16] No matter how diagnostically efficient a test may be, the patient-care-value of any single reported observation is diluted by the number of additional observations that are reported simultaneously. This is acceptable and unavoidable if the other information is of equal value. If it is not, it becomes a distraction and dilutes the physician's attention. This creates risk that the most valuable observation may be overlooked or be given insufficient thought to avoid misinterpretation. For these reasons, we must appreciate that even if we overcome limitations of space, personnel and equipment, the ability to produce an unlimited amount of information from clinical specimens is a distinct threat to the quality of those observations that have a greater value for patient care. Soon we will be able to produce almost unlimited numbers of measurements a day by the automated analysis of small samples of blood, urine, sputum or other body fluids that are collected with increasing frequency, or even continuously sampled by instruments attached directly to the patient.

Often, too much information is requested and produced because neither clinicians nor laboratorians will risk being accused of overlooking the improbable. Much attention has been drawn to this understandable attitude which dictates that no stone be left unturned in the search for any measure that despite cost could contribute to patient care. Enthoven has referred to this as "flat of the curve medicine" in which additional input produces no detectable output.[7] Laboratory scientists have long sought *zero error* as a goal in any kind of analysis, be it blood chemistry or identification of bacteria. Realization that this might never be achieved, and only approximated at an exponentially related increase in effort and expense, has created great controversy over whether 90, 95 or 99% accuracy is enough. Even in industry, there is some point beyond which further reduction in the number of unacceptable products that are produced can only be accomplished through an exponential increase in cost. Industry must establish where the breakpoint is, on the basis of the cost and quality of the product produced by the competition. Criteria must be developed that will objectively establish the degree of confidence that laboratory reports impart to diagnostic and therapeutic decisions. These involve both intra-laboratory precision and accuracy, and the efficiency of the test in establishing or excluding diagnoses.

Dudley reported that the increase in confidence that is established by increasing both the numbers of clinical observations and laboratory measurements can be measured statistically.[17] He stated that a surgeon could make a diagnosis of obstructive jaundice with 95% certainty by asking the patient two questions and making one clinical examination. Laboratory tests would increase the probability of a correct diagnosis to 97.5%. He expressed that the role of teaching hospitals is to reduce uncertainty and that this would inevitably lead to an increase in the number of tests that would be requested. Unfortunately, there is no data base for establishing the number of percentage-points increase in diagnostic confidence that is provided by any given number or combination of laboratory tests for the majority of diagnoses. It does seem certain that 100% confidence is an improbable goal and that the cost of approaching it cannot be justified.

The search for zero error in the laboratory is illustrated by the delay of several days that commonly occurs in reporting results of examination of microbiologic specimens until the minimum risk of error consistent with the state of the art has been achieved. Although confidence in the accuracy of the report increases with the passage of time, along with an increase in the expenditure of labor and materials, the value of the information for diagnosis and treatment may progressively decline and be negligible at the time it reaches the clinician.

Consideration must be given to reporting the analytical confidence limits around laboratory reports. Although this risks adding more to the already expanding volume of data to be screened by the physician, it would emphasize that limits of accuracy surround all reported information. It would also provide some measure of protection to the laboratorian who provides a preliminary report of a lower order of accuracy than the final report. For example, microbiologists are reluctant to report in writing bacterial species suggested by an examination of a gram stained direct smear. This results in such cryptic reports as "small pleomorphic gram negative rods" which is meaningful to the microbiologist but not to most clinicians. Data which we have collected and reported indicate that a more useful report of this observation which includes the probability that the presumptive identification will be confirmed by culture would be "Bacteroides or Hemophilus species." (44%)[18]

With evidence that optimum use is not being made of laboratory services, and that advancing technology is increasing this risk further, what measures can be taken to further evaluate and control the problem?

## Evaluation and Control

### *Private Incentive and the Regulators*

Much attention has been drawn to the capability of prepaid health programs to reduce costs while maintaining a comparable quality of care.[17] [19] Whether the medical profession will modify existing modes of practice rapidly enough to introduce the financial incentives that could provide such control before government assumes the entire responsibility is one of the great questions of our time. Public law 93-222 known as the HMO Act of 1973 has facilitated the development of such organizations. Alternatively, government management of health seems likely to bring us further increases in cost without providing adequate controls on utilization or uniform access to the system.

Legislation that Professional Standards Review Organizations (PSRO) be established represented a clear mandate to the medical profession to introduce controls on utilization and quality of services. At the present time PSRO is concentrating attention on length of stay. There is objective evidence that this has been reduced with infrequent disallowance of reimbursement for extended stay. So far the commissioner of HEW has not been required to issue a stay order which would enjoin reimbursement of a physician whose overutilization was considered a persistent problem.

PSRO activity has only begun to approach the evaluation of laboratory test utilization. Only physicians may direct or be members of a PSRO, but effective results in this area require the support and participation of allied health laboratory professionals, including microbiologists, chemists, and medical technologists. Preliminary efforts to evaluate laboratory utilization will be most effectively accomplished through retrospective medical care evaluation committees, also under the sanction of local PSRO's. A computer-based program has been developed in Ohio by the Medical Advances Institute (MAI) to establish the numbers and kinds of laboratory tests that would be considered useful for a variety of diagnoses.[20] Application of these criteria singles out medical records to be reviewed for potential laboratory misutilization.

Brook and his associates have reviewed the New Mexico Peer Review Program for evaluation and control of utilization of health services in the care of Medicaid patients.[21] Criteria were established for the kinds of laboratory tests which were used and the frequency of their application. Less than 5% of the laboratory tests performed failed to meet eligibility criteria but reimbursement was disallowed in these instances.

Other mechanisms by which attention may be drawn to overutilization of laboratory tests by PSRO will be review of hospital charges which exceed over $450.00 per day. This results in a review by a nurse and in turn by a physician to determine abuse. In such instances, the third party payer may disallow reimbursement of charges which it considers excessive. So far this has not occurred. Although not yet documented, there is increasing doubt that PSRO will be effective enough in the existing economic structure in which reimbursement provides no cost-reducing incentive to the physician. Within the structure of a prepaid health program it seems clear that the added incentive would accelerate and improve the efficiency of the control programs which have been introduced through PSRO.

Evidence that the State of Connecticut is making no assumptions that PSRO will be effective is found with the Commission on Hospitals and Health Care which has been charged with the development of criteria for the assessment of utilization and quality of care rendered to patients whose care is not reimbursed through Medicare or Medicaid. The commission is currently developing criteria for evaluation of use of ancillary medical services including the laboratory.

Insight is gained into problems that may be encountered in application of government imposed controls on laboratory use by review of the experience of the New York City Medicaid centralized laboratory proposal.[22] Consultants prepared lists of acceptable diagnoses for the performance of the most routinely ordered laboratory tests. Questionable claims were to be reviewed and reimbursement disallowed if indicated. Disputes would entitle both physicians and laboratories to formal hearings. Such hearings resulted in restitution of $150,000 to the city, but several million were saved by unilateral line by line claim reduction by Medicaid auditors. A dramatic example of misuse for which payment was disallowed were charges for antibiograms of indigenous flora in throat cultures. But the significant legal and ethical question was raised whether a laboratory could legitimately be made the economic victim of an improper request made by a physician. Should the laboratory mechanically process all tests which are ordered or should it attempt to review the appropriateness of requests for performance of tests by consulting with referring physicians? Could it then decline to process samples if there is evidence of misutilization which might lead to disallowance of reimbursement? The answer to these questions was thought to have profound implications for the future of clinical laboratories. In a legal opinion rendered by counsel to the New York City Department of Health, it was held that a laboratory could not evaluate the legitimacy of a request for a laboratory test without making a diagnosis of a medical condition. This was a violation of the Health Code of the City of New York which specifically forbids laboratories from making diagnoses.

## Evaluation and Control

*A Model:*

It had been apparent for many years that instances of inefficient use of resources were occurring in the Division of Microbiology, Department of Pathology of Hartford Hospital, and that this was simultaneously resulting in the reporting of information that was potentially misleading or useless. Much of this resulted from *improper submission* of specimens, including duplication, improper collection, wrong container, visibly apparent poor quality, excessive delay in submission, requests for tests of doubtful clinical value, and requests for examinations during off hours that could not be clinically justified as emergencies. Such specimens will be subsequently referred to as Group 1.

Another group of specimens (Group 2) included those which *appeared* appropriately submitted but which on microscopic examination or culture showed evidence of contamination with superficial indigenous or colonizing bacteria, or did not appear representative of optimum material for production of maximum useful clinical information. Improper collection was considered a contributing factor although it seemed likely that at least some of these specimens might have appeared satisfactory to the physician or nurse and that appropriate care may have been taken in proper preparation of the patient and collection of the specimen.

Medical publications and scientific meetings supplemented by laboratory improvement programs sponsored by both government and professional societies have placed increasing emphasis on more complete and thorough microbiologic examination of specimens. Application of this to these types of specimens seemed not only wasteful of laboratory resources but productive of information potentially misleading to the physician and perhaps of negative cost benefit for patient care.

Education in effective use of laboratory tests has long been viewed as the only acceptable control measure. We concluded that medicine is increasing so rapidly in technical complexity that it is no longer possible to compete for the available time nor expect that what is presented in a limited number of widely spaced educational sessions will persist long enough in the minds of physicians to ensure optimum use of laboratory resources. Indeed, there is no published evidence that education alone can provide effective and lasting control. We decided that it would become progressively more difficult for physicians to keep track of the factors affecting the efficiency of microbiologic tests, use them in the most appropriate stage of the disease, collect them from the most productive body site, and obtain maximum usefulness from the information reported. We felt that we had a responsibility to do more than just report results.

In 1969 a program containing measures described in detail elsewhere was cautiously introduced to evaluate the extent of the problem and introduce controls.[23,24,25,26,27] We found some support in Section 19-13-D32 of the Public Health Code of the State of Connecticut which states:

> "No specimen shall be examined if unsuitable for testing because of improper collection, improper preservation, apparent spoilage, excessive time lapse between collection and examination when applicable, or other reasons sufficient to render the findings of doubtful validity."

The total number of suboptimal specimens detected (Groups 1 and 2) were enumerated for 1974 and 1976. For convenience in tabulation properly submitted specimens that were processed completely were placed in a third group, and specimens from Groups 1 or 2 that were processed after consultation between clinicans and laboratory staff in a fourth group (see Tables 1 and 2). A striking decrease from 16% to 2% was observed in the number of *improperly submitted* (Group 1) specimens. This indicates that physicians and other patient care personnel can rectify improper submission practices if strict criteria of acceptability are applied in the laboratory.

Additional measures were introduced to detect specimens in Group 2 (*superficially contaminated specimens appearing* properly submitted). This was based on results of microscopic examination and culture. Respiratory secretions, fluids, and exudates from wounds or the uterine cervix were considered superficial and unsuitable for culture because of the probable presence of indigenous or colonizing bacteria unrelated to infection if an abundance of squamous cells and a paucity of leukocytes were observed. We requested fresh specimens by phone and in writing, and urged that effort be taken to avoid superficial contamination. Incomplete processing was applied to such specimens when multiple potentially pathogenic isolates were observed because we felt that many if not all represented colonization or contamination. Isolates which were seen both in the gram stained direct smear and in culture were considered of greater probable clinical significance than those that were absent from the smear. The latter isolates were not completely identified or tested for antimicrobial susceptibility. Again, reports were issued drawing attention to the relative probable clinical significance of the isolates and requesting recollection.

Although microscopic examination of urine is useful for detecting significant bacteriuria, it was not used for assessing the quality of urine specimens. Mixed cultures of urine were considered more likely to be contaminated than to indicate infection. These were reported with limited identification and without antibiograms with a request for repeat collection.

In all instances, specimens and cultures not completely processed were held for five days at 4 C and physicians were informed that processing would be completed if they would call to request it and indicate why this would be preferable to recollection. Only 260 requests (Group 4) were received for complete processing representing only 0.6% of all specimens of the type affected by these controls and only 2.6% of the approximately 10,000 superficially contaminated specimens detected each year (Table 1). Comparing 1974 and 1976, superficially contaminated specimens (Group 2) showed some decline from 27% to 22% of all fluids and exudates submitted. This suggests that

Table 1

OBSERVED NUMBERS OF IMPROPERLY SUBMITTED AND SUPERFICIALLY CONTAMINATED SPECIMENS*
DIVISION OF MICROBIOLOGY, DEPARTMENT OF PATHOLOGY, HARTFORD HOSPITAL

| | *Specimens Affected* | | | |
|---|---|---|---|---|
| | *1974* | | *1976* | |
| | *Number* | *Percent of Total* | *Number* | *Percent of Total* |
| GROUP 1 | | | | |
| *Improperly Submitted Specimens* | | | | |
| A. time of collection not given or delay >4 hours | 3360 | 10 | | |
| B. routine submitted at night | 1548 | 4 | | |
| C. inappropriate or non-specific request | 420 | 1 | | |
| D. duplication, improper containers, clotted, insufficient quantity | 372 | 1 | | |
| Group 1 Subtotal | 5700 | 16 | 894 | 2 |
| GROUP 2 | | | | |
| *Superficially Contaminated Specimens (appearing properly submitted)* | | | | |
| A. unsuitable for processing | 1292 | 4 | 1612 | 4 |
| B. limited processing | 8558 | 24 | 7556 | 18 |
| Group 2 Subtotal | 9850 | 28 | 9168 | 22 |
| Groups 1 and 2 Subtotal | 15550 | 44 | 10063 | 24 |
| GROUP 3 | | | | |
| *Properly Submitted Specimens, processing completed* | 19700 | 56 | 31606 | 76 |
| GROUP 4 | | | | |
| *Group 1 and 2 Specimens Processed after consultation* | | | 260 | .6 |
| TOTAL (Groups 1, 2, 3, 4) | 35250 | 100 | 41929 | 100 |

*lower respiratory secretions, cervical-vaginal and wound exudates, and urine.

laboratory reports of improper submission or of superficial contamination may have provided an incentive for collection of better specimens but that this alone does not ensure that optimal specimens will be received. It is probable that despite the best efforts to collect optimum specimens the quality of most can only be based on objective examination in the laboratory.

We conducted a cost analysis of this program in 1975.[24] Workload recording units recommended by the College of American Pathologists (CAP) were used. A saving of nearly $75,000 was computed. Subsequently we doubted that CAP units accurately reflected time expended on operations affected by our specimen evaluation and control program. Recently we conducted industrial time engineering measurements of these operations in our laboratory and applied them to the survey of specimens in 1976. This demonstrated a lower total saving of $18,045, 8% of the projected total cost of $235,288 if work had been completed on all specimens received.

Application of the newer cost accounting to the specimens submitted in 1974 using 1976 costs to eliminate the effect of inflation suggests that the total saving was closer to $35,000. This was nearly twice the saving achieved in 1976 but this was chiefly the result of the controls on processing of the Group 1 specimens which declined dramatically between 1974 and 1976.

These data suggest that significant reduction in the cost of clinical microbiology can be achieved by application of a specimen evaluation and control program. This does not result in layoffs of personnel but increases productivity so that little increase in staffing is required to accommodate the annual increases in volume that have generally exceeded the ten percent reduction in cost that we have demonstrated. The provision of more useful clinical

Table 2

DIFFERENCE IN COST OF PROCESSING IMPROPERLY SUBMITTED AND SUPERFICIALLY CONTAMINATED SPECIMENS WITH AND WITHOUT CONTROLS**
DIVISION OF MICROBIOLOGY, DEPARTMENT OF PATHOLOGY, HARTFORD HOSPITAL

| | GROUP 1 | GROUPS 2, 3 | TOTAL |
|---|---|---|---|
| | *Cost $* | *Cost $* | *Cost $* |
| 1974 | | | |
| Cost with controls | 9,519 | 154,335 | 163,854 |
| Cost without controls | 32,832 | 165,861 | 198,693 |
| Saving | 23,313 (12)* | 11,526 (6)* | 34,839 (18)* |
| 1976 | | | |
| Cost with controls | 1,495 | 214,354 | 215,849 |
| Cost without controls | 4,926 | 230,362 | 235,288 |
| Saving | 3,431 (1.5)* | 16,028 (7)* | 19,439 (9)* |
| Less cost of specimens processed after consultation (GROUP 4) | | | 1,394 |
| Total Savings | | | 18,045 (8)* |

* = percent total cost without controls.

** = lower respiratory secretions, cervical-vaginal and wound exudates, and urine.

information by this program may be more important than the savings to the laboratory. Indeed the greatest saving may result from prevention of errors in diagnosis and unnecessary antimicrobial therapy with the attendant risk of nosocomial infection and prolonged hospitalization.

To what extent can more efficient use be made of testing of other specimens? What about hematology and chemistry specimens?

### Improved Measure of Efficiency of Tests

More objective criteria must be developed to determine the comparative usefulness of both existing and proposed tests. This will permit more discriminating use of tests by clinicians and will also provide a more objective means of evaluating utilization by various review mechanisms. Galen and Gambino have defined terms for sensitivity, specificity, predictive value and efficiency.[28] These criteria may be applied to tests used for the diagnosis of the same disease to provide a measure of comparative usefulness. *Sensitivity* is the percentage of positives among all tests performed on diseased patients; *specificity* is the percentage of negatives observed among all tests performed on patients without the disease being sought.

*Predictive* value is expressed as either a *positive* or *negative* value. The *positive predictive* value is the percentage of all positive results which represent true positives (True positives x 100/True positives + false positives). It expresses the accuracy of the test to detect disease in afflicted patients. The *negative predictive* value is the percentage of all negative results which represent true negatives (True negatives x 100/True negatives + false negatives). This expresses the accuracy of the test to exclude disease in patients who are not afflicted. The effect of the *incidence* or *prevalence* of the disease in the population being tested on the diagnostic usefulness of tests is often neglected. Galen and Gambino draw attention to specious acclaim for the usefulness of a new diagnostic test when it is based on surveys of controlled and fixed populations of patients often containing equal numbers with and without disease. This produces a test population with a prevalence of 50%, a highly unrealistic condition. When the test is applied as a screening procedure to a population in which the prevalence is 1% or 2% the positive predictive value decreases. The negative predictive value or ability to exclude disease may remain high, but the overall efficiency is diminished.

A high positive predictive value is desirable when the percentage of false positives must be minimized because of the serious consequences of further evaluation or treatment of a patient without disease. A high negative predictive value is needed when serious consequences may occur if the disease is not detected and treated. Galen and Gambino define the efficiency of a test as the percentage of results that represent both true positives and true negatives (Efficiency = (True positives + True negatives) X 100/total tests). This expresses the overall accuracy of a test to separate patients with a disease from those without disease. An example of failure to apply these criteria was the premature acclaim given to a serologic test for gonorrhea which displayed 80% sensitivity and 95% specificity in comparison to culture which demonstrated comparable sensitivity, but 100% specificity. Application to populations containing equal numbers of patients with and without disease would yield a comparable positive predictive value for each, but application to a population with a prevalence for gonorrhea of only 3% yields twice as many false positive results as true positive results. The positive predictive value is only 33%; thus only one positive result out of three indicates gonorrhea!

The British National Health Service subjected new diagnostic and therapeutic procedures to a uniform system of evaluation resulting in approval by an officially appointed board. This prevented the introduction of the test for carcinoembryonic antigen which was made available in this country with less careful scrutiny and subsequently abandoned as an inefficient test. It can be anticipated that regulation will be applied to the evaluation of diagnostic tests similar to that now being applied to drugs and commercial diagnostic products.

### Disease or No Disease

Several significant problems are encountered in the attempt to develop objective criteria for the diagnostic efficiency of laboratory tests. The first problem is the inability to confidently separate patients into groups with and without disease to enable determination of *sensitivity* and *specificity*. If we are attempting to establish these values for a cultural diagnosis of gonorrhea, for example, we must recognize that the symptoms, signs and other available diagnostic criteria are not sufficiently pathognomonic to establish with certainty which patients are infected and which are not. This becomes more difficult in the evaluation of the predictive value of cultures for the diagnosis of lower respiratory infection. Lack of objective evidence of the *inefficiency* of culture of expectorated sputum has led to indiscriminate use of culture results in the diagnosis and treatment of lower respiratory infections. It makes a great deal of difference whether one is using the culture to make a diagnosis of pneumonia, or whether pneumonia is established on clinical grounds and the culture is being used to determine the probable etiologic agent. In a previous investigation,[29] we classified patients as positive for pneumonia when: (1) x-ray evidence suggested a pulmonary infiltrate, (2) several positive auscultatory signs consistent with pneumonitis were found, (3) the patient was febrile, (4) produced moderate amounts of purulent sputum. The negative groups were patients in whom none of these criteria was found. This establishes a value of 100% for both the sensitivity and specificity of the clinical criteria for the diagnosis of pneumonia. Some investigators consider bacterial pneumonia established only when blood cultures are positive, but many cases of pneumonitis probably occur without bacteremia. In the absence of a positive blood culture or evidence of circulating microbial antigen, the only way to establish a more confident pathologic diagnosis would be to perform a biopsy of the affected portion of the lung. In our study, 56% of patients producing sputum were classified as having pneumonitis. Cultures were positive for potential pathogens in 74% of the affected patients and were negative in 38% of the unaffected patients. This yields a positive predictive value of 60% and a negative predictive value of 54%. The efficiency of the test is 58%. Therefore, the ability of a sputum culture to predict the presence or absence of pneumonitis on the basis of the isolation of potential pathogens is only 8% better than would be obtained by the flip of a coin!

### Prevalence or Frequency of Disease: Unknown or Variable

The second problem is that clinicians may apply tests to patient populations in which the prevalence or incidence of disease is unknown and may vary widely. If estimates of efficiency are based on any previously observed or reported prevalence, physicians should realize that the positive predictive value of a test with a specificity of less than 100% will decrease dramatically as the prevalence or frequency of disease decreases in the population being tested. Perhaps laboratories should provide physicians with tables of sensitivity, specificity, predictive value, and efficiency for all tests offered for several different prevalence or frequency levels so that physicians can appreciate the relative usefulness of the test when ordered selectively or as a screen.

### Temporal Relevance to Disease

Thirdly, there are instances of requests for analyses which could not be expected to be efficient for diagnostic use in relation to the temporal stage of the disease. For example, examination of blood for Leptospira is relatively useless in patients who have been sick for several weeks; organisms may be demonstrated only during the first several days of the illness. The microscopic agglutination test for Leptospira is over 98% efficient after the second week of illness but displays practically zero efficiency during the first five days.

### Laboratory Cost and Efficiency: Health Care Value

The health care benefit in terms of dollars spent for value accrued cannot be based on the relatively academic measures of diagnostic efficiency that have been presented in the preceding paragraphs. Marked differences in the cost of performing tests result from variations in the skill, time, equipment and materials that are required for their performance. For example, the microscopic agglutination test for Leptospirosis is more sensitive than the macroscopic test but it is more difficult and expensive to perform, hence the less efficient macroscopic test is commonly used.

### Clinical Cost of Laboratory Tests

Numerous clinical factors contribute expense in addition to the laboratory cost of performing a test affecting further its net health care value. Clinical expense is incurred in the time required for physicians and allied health personnel for preparation, collection and transmission of the specimen. Additional expense results from the added duration of hospitalization that may result from delay in reporting of results. For example, the microscopic agglutination test for Leptospirosis previously referred to is not only expensive for the laboratory to perform but is usually only available from reference laboratories resulting in delay in reporting. Delayed reporting contributes to the cost of delayed diagnosis, treatment and hospitalization. A highly efficient test that produces a greater frequency of complications may lead to prolonged hospitalization and other therapeutic measures which render its net health care value lower than that of a less efficient test. It is difficult to place a monetary value on the greater discomfort that may be caused, either in the collection of the specimen or in the complications that may ensue, but this certainly diminishes the net health care value of the test.

For example, the efficiency of culture of transtracheal aspiration for the diagnosis of pneumonitis is 91%,[30] substantially greater than the 58% quoted above for culture of expectorated sputum. But most physicians continue to depend on examination of expectorated sputum because they have adjudged that the greater efficiency of the transtracheal aspirate is offset by the greater discomfort to the patient, the morbidity, and the requirement that the physician expend time on the performance of the procedure.

The same may be said for detection of *Pneumocystis carinii* in tracheal secretions or sputum instead of the more efficient lung or bronchial biopsy; or analysis of a clean catch urine specimen despite the more efficient results obtained by examination of a specimen collected by suprapubic aspiration. On the other hand, it is nearly impossible to obtain urine specimens of good quality from small children, hence the inconvenience and invasive aspects of the suprapubic aspiration render this alternative more desirable.

The difficulty of integrating laboratory and clinical cost with diagnostic efficiency to establish justification for a test is illustrated by a preliminary study which was conducted in our laboratory to determine the value of microscopic examination of specimens submitted for urinalysis that yield negative chemical tests for hemoglobin and albumin from patients with no past history or signs or symptoms of genitourinary or renal disease on admission to the hospital. The benefit of conducting such examinations has been examined and debated by others.[31, 32] If a health care value could not be demonstrated we proposed to offer two kinds of urinalysis. A *screening* urinalysis would be performed in which microscopic examination would not be performed on chemically negative specimens. We would offer a *diagnostic urinalysis* that we would suggest be ordered on any patient with a history or signs and symptoms of genitourinary or renal disease. These specimens would be carefully examined microscopically despite results of chemical tests.

Among 96 patients yielding specimens which gave negative chemical results but demonstrated cells or casts only two were found in whom a microscopic urinalysis revealed cells and/or casts which led to a diagnosis of disease that otherwise might have been delayed or missed. Positive microscopic findings were ignored by physicians among 87, further investigation being conducted on only 9 patients.

Extrapolation of these data suggest that abandonment of microscopic examination of urine under the conditions described might result in delay or failure to recognize disease in about 175 patients a year in our hospital. The cost and discomfort which this implies is unknown. We have always assumed that any expense which speeds recognition of disease is justifiable but Dodge has reported no cost benefit from early detection of renal disease in children.[33] The potential saving for our laboratory is in the range of $12,000 representing an expenditure of about $70.00 per case detected. The cost of investigating renal disease further in the projected 600 patients in whom no disease would be found should be included. Based on review of records in the seven patients included in the study, two additional confirmatory tests might be ordered at an average cost of $10.00 per patient yielding a total cost of $6000. Distributed among the diseased patients detected (175) this increases the cost for their detection from $70 to over $100 ($6000/175 = $34 + $70 = $104). Viewing this another way, the community might be spared over $18,000 of hospital expense if this test were discontinued without sacrificing any proven benefit to the patients who diagnosis might be delayed or overlooked.

### Laboratory Tests, Health Care Value, and "Decision Analysis"

Jellife has commented on the frustration that is encountered in the attempt to apply objective analysis to the implications for health care value of alternative clinical decisions that include the ordering of laboratory tests, stating that "it is unpleasant and difficult to attempt to put specific numbers on such things which affect us all so deeply but to continue to act intuitively as we have is to continue to deny the fact that we actually have been grading or comparing such things in a relative manner all along."[34]

He concluded that wisdom is good in the absence of quantitative data but that development of the latter should significantly sharpen clinical judgement and improve patient care. Weed expressed the helplessness felt by those outside of the medical profession who have been increasingly called upon to evaluate the way in which health resources are being used: "Where are we going? Community trustees and leaders, and the general public will no longer be able to mold their actions from isolated personal concepts of the art of medicine as revealed to them through their personal surgeon or internist or through their radiologist or pathologist neighbors. In the past, these very physicians developed their limited points of view from random incomplete medical and financial data on the few patients who stumbled to their doors, selected because of financial aid and social forces with which the physician was only vaguely aware."[35]

Enthoven[7] has emphasized the "bias in favor of more care, and more costly care, whether or not it helps the patient" and borrowed Fuch's phrase " . . . medicine should consider the possibility of contributing more by doing less."[36] Therefore we should get on with development of criteria and methods for evaluation and control of laboratory use and concentrate on the production of that information which is of the greatest predictable medical value while minimizing that which is not. This will require incentives for more intense cooperation between clinicians, laboratorians, third party payers and regulators.

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# Statistical Analysis of Factors Predisposing to Candiduria

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**ABSTRACT—In order to evaluate potentially removable factors that predispose a hospitalized patient to candiduria, the medical records of all patients who developed this problem during a four-year period were reviewed. Each of these patients and a randomly chosen matched control patient were then evaluated for the presence or absence of ten factors that have been mentioned in the literature that may increase the likelihood of colonization or infection with Candida. Of the ten items evaluated (six antibiotics, corticosteroids, peripheral intravenous catheter, central venous catheters and other drains) statistically significant ($p < 0.05$) relationships in the development of candiduria occurred only in patients with peripheral intravenous catheters and individuals receiving cephalothin or gentamicin.**

### Introduction

Candida species have long been recognized as common saprophytes in man, yet it is only recently that they have become important pathogens.[1] Although several reviews have mentioned many factors that are capable of converting this fungus from a saprophyte into a pathogen, these factors have not been statistically studied through the use of a randomly selected match-control population. In order to objectively evaluate and quantify these often mentioned risk factors, we reviewed their association with candiduria in this fashion.

### Materials and Methods

Data were obtained from the hospital records of all patients who developed candiduria from July, 1971 to July, 1974. Only those patients whose urine grew *Candida albicans* as the sole pathogen in more than one clinical specimen were included in the study. Charts were selected at random from the overall hospital population admitted during the same time span and were matched for sex, age, race, duration of hospitalization and hospital service. Since all the patients who developed urinary candidiasis had indwelling Foley catheters, the presence of a Foley catheter was also one of the matching factors.

Factors examined on all records included the following: a) peripheral intravenous catheters (plastic and steel); b) central venous pressure catheters in the subclavian vein; c) intravenous hyperalimentation; d) drains other than Foley catheters (nasogastric tubes, gastrostomy tubes, etc.); e) antibiotics (ampicillin, gentamicin, cephalothin, clindamycin, chloramphenicol, and penicillin, subdivided into 3 groups: none, drug for 7 days or less, and drug for more than 7 days); and f) corticosteroids (subdivided into groups similar to those for antibiotics).

One to one pairing of the controls with "experimentals" was done to insure group similarity on each of the variables for which they were matched. The goal was not to test one to one pairs, but rather to compare the experimental with the control group. The data from both groups were examined in comparison by chi square analysis with the Yates correction factor applied to all chi square tables with one degree of freedom.

### Results

Those patients who developed candiduria (Table 1) demonstrated statistically significant ($p < 0.05$)

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Table I

STATISTICAL ANALYSIS OF FACTORS PREDISPOSING PATIENTS TO CANDIDURIA (EXPERIMENTALS) VERSUS MATCHED CONTROLS

| *Variable* | *Not Present* | *Present* | *Severe* | *Significance (p)* |
|---|---|---|---|---|
| 1. Peripheral IV's* - E | 6 | 69 | | .009 |
| Peripheral IV's - C | 19 | 56 | | |
| 2. Cephalothin - E | 46 | 13 | 16 | .004 |
| Cephalothin - C | 51 | 21 | 3 | |
| 3. Gentamicin - E | 55 | 10 | 10 | .02 |
| Gentamicin - C | 68 | 4 | 3 | |
| 4. Corticosteroids - E | 63 | 4 | 8 | .21 |
| Corticosteroids - C | 65 | 7 | 3 | |
| 5. Ampicillin - E | 56 | 10 | 9 | .23 |
| Ampicillin - C | 62 | 4 | 9 | |
| 6. Penicillin - E | 70 | 4 | 1 | .39 |
| Penicillin - C | 73 | 1 | 1 | |
| 7. Chloramphenicol - E | 71 | 3 | 1 | .60 |
| Chloramphenicol - C | 73 | 1 | 1 | |
| 8. Clindamycin - E | 69 | 4 | 2 | .64 |
| Clindamycin - C | 70 | 2 | 3 | |
| 9. CVP** - E | 47 | 28 | | 1.00 |
| CVP - C | 48 | 27 | | |
| 10. Other drains - E | 43 | 32 | | 1.00 |
| Other drains - C | 42 | 33 | | |

* IV's - intravenous catheters
** CVP - central venous pressure catheters

predisposing factors in the following categories: gentamicin (p = 0.02), cephalothin (p = 0.004) and peripheral intravenous catheters (p = 0.009).

Twenty of the 75 patients in the candiduria group died, while only ten of the 75 control died, which is not a statistically significant difference. We also evaluated patients in the same manner for the presence or absence of particular chronic disease states, including diabetes mellitus, cardiovascular disease, malignancy, hypertension and obesity. There were no statistically significant differences between those who developed candiduria and those who did not.

## Discussion

Our retrospective survey of patients who developed candida infections of the urine indicated that statistically significant results can be obtained by employing methods which quantify risk factors. All of these factors do not equally exert their influence on an individual patient. While a single factor may alter the susceptibility of a patient to a given microorganism it is the combination of factors which proves to be most detrimental, by increasing the likelihood of infection with fungi or other opportunists.

To decrease the chance of a patient's developing candiduria, the physician should, if possible, remove peripheral intravenous catheters and avoid broad spectrum antibiotics, like cephalothin and gentamicin, since these factors were found to be significantly related to the development of this type of infection. The lack of association of candiduria with the use of penicillin, ampicillin, chloramphenicol or lincomycin appears to indicate that these antibiotics are not so important as predisposing factors in the development of candiduria.

Candiduria may be eradicated by the removal of intravenous catheters or discontinuation of cephalosporins and aminoglycosides. Specific antifungal drugs like amphotericin and flucytosine need not be given if such relatively simple maneuvers are initially undertaken, as has been suggested.[2] In fact, candiduria in itself may not be important in the presence of these underlying factors since the mortality rate in the candiduria group was not greater than in the "controls." This observation makes it difficult to evaluate the efficacy of any therapeutic maneuvers for candiduria, or if the need to avoid it in these kinds of patients is indeed necessary.

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# WORKING FOR ALL....

This year is a very special one because it marks the 50th anniversary* of the first prepaid hospital plan in the country — the forerunner of the Blue Cross and Blue Shield concept as it is known today.

In Connecticut, the Blue Cross and Blue Shield Plans are not quite that old, but their work — for many years independent of each other, and today working as one — have always had a twofold purpose:

- To provide financial peace of mind to those in need of health care services.
- To attempt to instill good health habits in everyone — member or not.

*In 1929, J.F. Kimball, executive vice president of Baylor University, initiated the principle of health cost coverage.

*While modest in scope and limited to only one group of subscribers, the fundamental soundness of the idea, together with the work of thousands of dedicated people, ultimately enabled tens of millions of Americans to achieve protection from the costs of illness and accidents.*

*Here in Connecticut, a plan for hospital care was incorporated in September 1936, with the first group enrolled six months later.*

*In December 1948, Connecticut Medical Service (CMS) was created for the purpose of establishing a non-profit medical/surgical service plan.*

*And on August 1, 1977, Connecticut Blue Cross and CMS began consolidating their efforts to more efficiently provide broader health care coverage.*

*For everyone.*

Commemorating
fifty years
Working for a
healthier America

ALL OF US HELPING EACH OF US

**Blue Cross
Blue Shield**
of Connecticut

# Hospice—A Concept of Care in the Final Stage of Life

SYLVIA A. LACK, M.B., B.S.

**ABSTRACT—Hospice is a specialized health care program emphasizing the management of pain and other symptoms associated with terminal illness. Hospice makes the family the unit of care, centers much of the caring process in the home, and seeks to enable the patient to carry on an alert and pain-free existence.**

**Pioneered in America by the Connecticut Hospice, and recently endorsed by the American Medical Association, the movement now includes over 200 developing hospices across the United States. Out of the British and New Haven experience have evolved program characteristics essential to the delivery of effective and appropriate care.**

The Hospice programs which exist in Britain and in New Haven, Connecticut, have grown out of the needs of patients and families in the communities they serve. A multidisciplinary approach which provides medical and health services for the palliative care and treatment of patients with a terminal illness and of their families, the concept has recently received approval by the American Medical Association.[1] The total hospice program provides integrated home health care, inpatient and outpatient care, and bereavement period follow-up for survivors.

The Connecticut Hospice, a non-profit corporation, pioneered this type of care in the United States with the start in March, 1974, of the home care component. A 44-bed inpatient facility is under construction and is due to open in the fall of 1979. During a three-year contract from the National Cancer Institute, The Connecticut Hospice provided care for 414 patients and families. Two thirds of these patients were enabled to die in their own homes. Most patients in America (80 percent) die within an acute or extended care facility. The median life span after referral was 70.5 days with a range of 1 to 630 days (one patient has recently died four years after original referral).

There are presently over 200 developing hospices across the United States. Emergent hospices must first assess the needs of people in their own area, survey the available resources, and tailor a program to meet the local conditions. It is possible that such a study will reveal that a hospice is not needed in certain communities. However, if a decision is made to start a hospice, it must be realized that this involves a commitment to provide all the necessary elements of care now recognized. These include symptom control, emotional and spiritual support, home care, a bereavement program, and an informal, relaxed approach to the patient and family. It is not only the patients who need help. Chronic illness, a death in the family—each has wide repercussions; it is thus the whole family, and not just the patient, who must be the unit of care.

The major goals of The Connecticut Hospice are to:

1. Provide physical and psychological care for the patient suffering from an illness diagnosed as terminal.
2. Care for the families of dying patients during illness and bereavement.
3. Provide a support system to help people live effectively in the face of impending death.
4. Be a center for the teaching and study of terminal care in the United States.

St. Christopher's Hospice in London, England, cares for people suffering from cancer or other long-term illness.[2] Many of them die in the hospice though about 12 percent are able to go home after their pain and other symptoms have been controlled. Patients

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with a terminal illness need more care than do those whose sickness can be cured. This care must be the best that skilled nursing and medicine can provide, and must keep abreast of every modern development. Such care is provided under a total program embodying the following essential characteristics:[3]

1. Coordinated home care-inpatient beds under a central independent hospice administration.
2. Patient/family regarded as the unit of care.
3. Physician-directed services.
4. Provision of care by an interdisciplinary team.
5. Control of symptoms (physical, sociological, psychological, spiritual).
6. Services available on a 24-hour-a-day/7-day-a-week/on-call basis with emphasis on availability of medical and nursing skills.
7. Utilization of volunteers as an integral part of the interdisciplinary team.
8. Bereavement follow-up.
9. Structured staff support and communications system.
10. Patient/family acceptance on the basis of health needs, not ability to pay.

### Coordinated Home Care-Inpatient Beds Under a Central Independent Hospice Administration

The hospice concept—as brought from Britain to the United States—implies a separate free-standing facility for care of patients with a terminal illness. Indeed Dr. C. Saunders, Medical Director of St. Christopher's, has written that "those patients who do not need the manifold resources of a large hospital and who cannot be cared for at home are frequently better cared for and happier in a smaller, specialized unit."[4] It is not difficult to argue that a free-standing hospice with all the necessary elements of care is needed as a focal point for the nation, a demonstration of the total program.

The 44-bed facility due to open in the fall of 1979 in Branford has been designed to serve the state of Connecticut. Patient/families from the entire state who meet the criteria will be eligible for admission upon referral by their attending physician. Medical responsibility for the patient's care while in the facility will normally rest with the hospice physicians, particularly for patients from distant locations. Upon discharge they will return to the primary medical care of their own physician. Referring physicians may visit patients at any time, confer with hospice physicians regarding care and treatment, review charts, and write notes on progress sheets. Good communication and close teamwork make it possible for the hospice physicians to work interchangeably, giving the patient continuity of care. It is important that community physicians understand the concept of hospice care and that a level of trust be reached between them and the hospice physicians.

Clearly, however, free-standing hospices are not the only model for terminal care; there is no doubt that establishing free-standing facilities is time-consuming. In the United States it involves certificate-of-need approval from a planning agency; in view of the overbedding of the facilities in many states this is a laborious process. We must explore all possibilities to bring relief to suffering patients and families as soon as possible, but this urgency must not force us into accepting substandard care. The Palliative Care unit at the Royal Victoria Hospital in Montreal,[6] and the Symptom Control Team in St. Luke's Hospital of New York have pioneered in exploring other ways of successfully providing hospice care. Any group planning a hospice unit within a hospital must ensure that elements of the program not usually available in these settings are provided. Extra funds will be needed for adequate medical direction, recruitment of volunteers, education of staff, and 24-hour-a-day/7-day-a-week availability of a Home Care Service. Most important, even if a small part of a larger institution, the hospice unit must retain full autonomy of patient care decision making.

Many patients want to stay at home if there is nothing more that the hospital can offer them. Most cannot stay at home because the care they need in terms of symptom control, medical attention, nursing expertise, and social work help, is all hospital-based. If this care is taken into the home, families do the most amazing things! They want to help, and they ask for support to enable them to do what they are willing to do. The consistent pattern which I have seen in Britain and in New Haven is that a large number of families desire to care for their dying relatives at home, and that a large number of dying people wish to stay at home. What they need is the support to enable them to do that. What is such support? A lady whose father had just died defined it thus: "Hospice was my backbone; they held me up so that my hands were free to care for my father."

### Physician-directed Services

Patients and families consistently report feelings of medical abandonment. All too frequent is the sad comment, "Well, I seem to have lost Dr. Q. somewhere along the way." There is a time in a patient's illness when the health care professionals begin to feel that there is nothing more they can do, and it is this loss of their doctor's interest that patients fear most. When a patient elects to remain home for his last weeks, this decision frequently cuts him off from effective medical care because many physicians do not make home visits. We see many patients seriously ill, suffering from vomiting, pain, and other controllable symptoms, bedfast at home, who have not seen a doctor for many weeks. Others find that if they do struggle to the doctor's office or a hospital clinic they see a resident, while the person they regard as their doctor is with patients who can be cured. It is vital to the psychological well-being of the patient with terminal illness that the physician is a key figure in the care he receives. This is not only psychologically important; it is also essential to his physical well-being.

In existing hospices the doctors are focal points because of their medical skills and because they provide inspiration, leadership, and a link with the medical community. Medical direction of the program is critical to ensure delivery of appropriate treatment. Fears were initially expressed by New Haven physicians, that, once referred to Hospice, patients would be on a "one way escalator to death" regardless of improvements in their condition or new disease treatment advances. Hospice showed that competent medical overview identifies misdiagnoses, remissions, complications amenable to hospital treatment, and patients referred too early in the course of their disease.

In Hospice the physician is involved as a member of the caring team. His or her essential contribution is reviewing the diagnosis and thereafter relieving troublesome symptoms.

### Symptom Control

There is far too much talk in death and dying circles in this country about psychological and emotional problems, and far too little about making the patient comfortable. Any group concerned with service to the dying must be talking about smoothing sheets, rubbing bottoms, relieving constipation, and sitting up at night. Counseling a dying person who is lying in a wet bed is ineffective. Such concerns loom large in the lives of critically ill patients and must be of importance to the physician if the physician is to treat the whole person.

If people are cared for with common sense and basic professional skills, with detailed attention to self-evident problems and physical needs, then patients and families themselves can cope with many of their emotional crises. Without pain, well-nursed, with bowels controlled, mouth clean, and a caring friend available, the psychological problems fall into manageable perspective.

Any physician who is dealing with a number of patients with terminal illnesses must become interested in symptom control and skilled in the management of the various types of physical distress. Sadly, the terminal stage has been defined by some as beginning at the moment when the doctor says, "There is nothing more to be done" and then begins to withdraw subtly from the patient. Patients, of course, are very well aware when this happens. There is never a time when "nothing more can be done." There may indeed be nothing more that can be done to cure the disease, but there are always further measures to be taken for the comfort of the patient and family.

I will illustrate this approach by a discussion of the problem of pain. The pain of a terminal illness is not just a physical pain. By the time the patient has reached the terminal stages of his disease, he is suffering from many other types of pain, including mental, financial, social, and spiritual. One needs to pay attention to the whole person if one is to affect the complaint of pain. The aims of treatment are to identify the etiology, prevent pain, help the patient be alert, maintain normal affect, and maintain easy administration.

Identification of the etiology is a clinical diagnosis, and investigations should be limited to a basic few; however, it must be remembered that not all pain suffered by the cancer patient is due to the cancer.

The pain should be controlled so that it will not return; continual pain control is the aim. When the blood sugar of diabetics is controlled, the physician does not wait for coma to develop before giving more insulin. Instead, it is determined what insulin dose prevents acute manifestations of the disease. This dose is then administered on a regular basis. The same principle of regular dosage is used in chronic pain control.

An alert patient with normal affect relates normally with his family and friends; drugs are not used to produce euphoria. Sedation can be avoided by careful titration of the analgesic dose.

Finally, a treatment is needed which is easy to administer and which gives greatest ease and freedom of movement. At Hospice, 85 percent of patients are managed on oral drugs until their death. Forty percent of all cancer patients can be expected to have severe pain. Such pain must be thought of in terms of anxiety, depression, and insomnia as well as physical pain. (Figure 1). Unless pain is reviewed with all of these components in mind, control will not be achieved. Anxiety and depression are part of the chronic nature of pain. The patient is anxious about the pain returning; s/he is anxious because of the meaning of the pain. This is not the acute pain doctors are trained to deal with. It is not like the pain of a

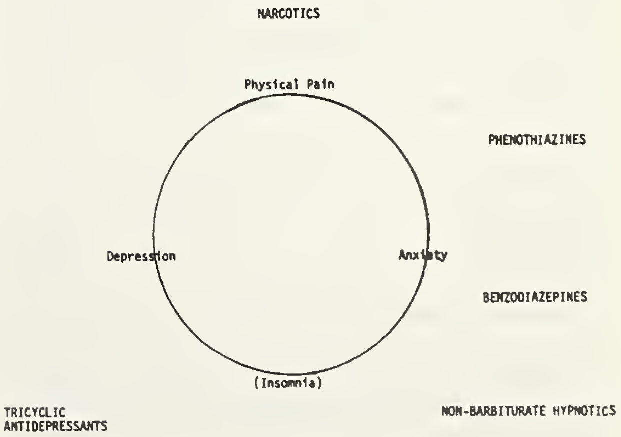

Figure 1

toothache or childbirth or appendicitis—pains which have a foreseeable end. Acute pain may serve a purpose by warning of a malfunction. Pain for the cancer patient has a sinister meaning. If I wake up in the morning with a stiff neck I assume I slept in a draft. The cancer patient wakes up in the morning with a stiff neck and assumes she has metastases. The degree of perceived pain is totally different in these two situations. One must take into account the anxiety that these patients are suffering, along with the chronic depression caused by chronic pain.

Narcotics should be reserved for severe pain, but patients in pain should not be required to wait until they have only hours or days to live. Narcotics should be started when non-narcotic medication, used correctly, and other measures, such as nerve block or radiation therapy, have failed to control the pain. At Hospice, narcotics are almost always combined with a phenothiazine, routinely prochlorperazine. A phenothiazine is used with the narcotic for several reasons. First, it potentiates the narcotic so that a lower dosage of narcotic can be used; second, it is an antiemetic, counteracting nauseant side-effects of the narcotic; third, it is a tranquilizer, which helps with the anxiety component of pain. Other anxiolytic drugs such as benzodiazepines—Valium and Librium—may be used in combination with a phenothiazine or, very rarely, alone with the narcotics. Tricyclics are used as antidepressants. The physician needs judgment and experience to treat the depression of terminal illness. Depression may be a perfectly appropriate and necessary reaction or stage—a response to the realization of death. Because somebody is depressed, the doctor does not automatically rush in with an antidepressant; but if depression is an identifiable component of perceived pain, the addition of a tricyclic antidepressant may conquer that last vestige of pain.

We look for the dose that controls pain but does not sedate the patient. This may be within a very fine dosage range. If a narcotic is increased in jumps of 10 mg., the optimum dose may be missed because a one or two milligram adjustment is needed. One of the reasons that we give narcotics as an oral liquid is because a liquid can be titrated more finely than tablets. There are two ways in which this can be done: if the patient is in severe pain requiring immediate relief, even at the cost of sedation, a high dose is initiated. The patient and the family are informed that sedation is expected for two or three days. The dose is gradually reduced until the pain returns; a small increase and the pain-free interval is achieved. The more usual way of accomplishing this, especially on home care, is to start with a low dose of narcotic and build up gradually. The sedative effect of the narcotic wears off in two to three days, sedation is largely avoided, and an appropriate dosage regimen is reached.

In New Haven, morphine is dissolved in cherry syrup. This is called the "Hospice Mixture." It is usually combined with a phenothiazine. Cocaine, alcohol, or chloroform water are not included as in the classic Brompton cocktail. In particular heroin is unnecessary for good pain control in most cases; morphine is a satisfactory alternative as has been shown by Twycross at St. Christopher's Hospice.[7]

Other less specific aspects of pain control are important, such as distraction and other activities. Pain control is not merely a matter of writing a prescription.

The physician should have a virtually inexhaustible store of remedies for all the common problems in terminal disease. We find it useful to take a problem-oriented approach, treating each symptom almost as a disease in itself to be diagnosed and treated. Thus the patient becomes not Mr. Doe with incurable cancer, but Mr. Doe—the man with severe pain for which we can do a great deal. This enables the physician, as part of the team, to approach the patient with an optimistic, realistic attitude—and the effect of such an approach on the patient and family may be dramatic.

### Twenty-four-hour-a-day/7-day-a-week Availability

Emergencies all too often occur at night and on weekends when help is scarce. A husband who reluctantly placed his wife in a convalescent home for the last three months of her life described the kind of stress that forced her admission. He remembered, with vivid horror, the time her gastrostomy tube fell out at 3:00 a.m. and he tried to replace it according to phone instructions from an unknown emergency room doctor. How easily one physician home visit could have saved three months of institutional custody.

The fear and anxiety engendered by even the thought of such a crisis causes many families to give up home care. Having emergency care available in the home gives families and patients the security and support they need to continue.

### Interdisciplinary Team

Individuals often have a limited view of patients with a terminal illness and fail to address the complexity of the problems they present.

The management of the dying must be a team concern. The team includes the patient—often the source of greatest strength—his family, doctor, clergyman, nurses, social worker, volunteers, and other health workers. Continuity of management forms an important element of the total care. Interdisciplinary care must not be a synonym for fragmented care in which the bewildered patient does not know which physician is in charge or who is dealing with which problem. Real teamwork mandates that interdisciplinary personnel sit down together at regular conferences to work out a plan of care for the patient and family, and to learn each other's languages.

### The Family as the Unit of Care and Bereavement Follow-up

Objective support for this concept now comes from the evaluation study of The Connecticut Hospice by R.W. Buckingham. He indicates that the family member primarily carrying the burden of care suffers more anxiety, depression, and social malfunctioning than the patients themselves.[8] This finding applied to both Hospice and non-Hospice groups.

The main burden of home care falls on families and friends. These caregivers must receive adequate help and advice. The sympathetic listener who indicates understanding of the tension and frustration is an essential member of any effective team. Families must be made aware of the help that is available and assured of its arrival when needed. Nothing contributes to the "end of the tether" syndrome as much as the sense of being hopelessly beleaguered when nobody cares or wants to know. When inpatient admission is required it should be made possible within twenty-four hours, preferably immediately. Failure to provide timely aid leads to admission to a long-stay facility earlier in the illness. Such an admission often indicates too little help at home, but is commonly construed as yet another manifestation of uncaring relatives and disintegrating family systems.

Upon the patient's admission to an inpatient facility, the family which has been nursing the patient at home has invaluable experience to offer the professionals on the precise details of care: which is the most comfortable position, how frequently medication must be given to keep the pain under control, certain expressions unique to this particular patient. A 19-year-old was labeled confused and heavily sedated after he had repeatedly cried out in a terrified fashion that a big red engine was in the room. It was only after his death that the family told how it was the fire service who brought his oxygen to the home when he had breathing difficulties. He was trying to communicate to the hospital staff needs for oxygen and for help in breathing. He was not asking to be sedated.

After the death, the dismembered family lives on and may need ongoing aid to prevent the morbidity and mortality of grief described by Parkes.[9] Indeed, the health care staff also live on, and attention to their need to grieve is essential if this demanding work is to continue.

### Structured Personnel Support and Communication Systems

Here is another area where much study remains to be done. From these five years experience we know that if personnel are to continue to form close human relationships, the very foundations of hospice work, they must experience a kind of support and working environment not usually found in health care agencies. But within this general framework there are many unanswered questions. How should we select staff? Why do people come to work at Hospice? Why do they stay? Why do they leave? We have some tentative working opinions on these important matters and some functional approaches. Quality inservice education, the team approach, administration-clinical communication, regular conferences—formal and informal—an occasional "Day Away" for all staff, an enthusiastic dedicated volunteer corps, acceptance of grief and tears, monitoring workloads to prevent overzealous "burn-out" syndrome, part-timers—these are just some of the mechanisms we use for staff support. Much needs to be learned.

### Volunteers—Used as an Integral Part of the Home Care Team

"You medical folk are all very nice," said one husband, "but the *real* people are better." At St. Christopher's and St. Luke's in England, volunteers are effectively utilized as an integral part of an interdisciplinary team. The Connecticut Hospice has extended this principle by taking volunteers into the home, where they play an indispensable role in keeping the patient at home.

#### Example 1

An exhausted wife was in tears because she could not continue her husband's 24-hour care, and admission to hospital seemed unavoidable. Emergency introduction of two volunteers to "patient sit" enabled her to spend a full twenty-four hours in a neighbor's home and return refreshed with long-term help promised from her church congregation.

#### Example 2

A 67-year-old man died at home; his wife carried the full brunt of his care while he was bedridden for the last two months of his life. The highlight of her week was the weekly car drive with one of our male volunteers. Sometimes they did errands, but more often they would take a scenic drive. The evening before the trip Mrs. G. would be smartly dressed with make-up on. This well-groomed turnout would last for two days after the trip; then she would gradually slip back into the dowdiness characteristic of the essentially homebound—but right on schedule, the day before her next trip, she would be all spruced up again. On other days, volunteers were also in the home helping with the housework or sitting with Mr. G. while his wife popped out to do the shopping. There is no doubt that without them, Mr. G. would not have died at home.

The volunteer is uniquely able to help the patient maintain or re-establish his sense of self-worth. The dependency and reduction in functioning created by a disability eats away at self-esteem. Withdrawal of some professionals and friends as they try to cope with their own feeling of inadequacy, reinforces the patient's diminishing sense of personhood. The volunteer, by forming a close friendly relationship, can counteract this demeaning process. We give our volunteers basic orientation to the program but do not attempt to turn them into "counselors" for the dying. Their special value is as a person with whom the patient can identify. He sees them as "people like myself." He discusses many areas with the lay volunteer that he does not discuss with the professionals.

**Patients should be accepted to the program on the basis of health needs, not ability to pay.**

Patients are accepted on the basis of health care need, not on ability to pay. No British hospice discriminates against patients because of their financial status, and American hospices must also strive to uphold this high standard of care. We cannot avoid responsibility in this area by reference to socialized medicine. Most of the hospices in Britain are not under the National Health Service. They are financed by a combination of charitable donations, patient contributions, and government reimbursement.

Increasingly effective therapies, which slow down—but do not cure—the disease, make it inevitable that persons with chronic degenerative diseases will live longer in a dependent state. Physicians can take a more positive interest in their problems, and realize the satisfaction of successfully meeting the management challenge presented by these patients and their families. Hospice care represents a successful synthesis of recent developments in caring for these patients whose life expectancy is limited to weeks or months. By bringing to bear a full complement of paid and unpaid health disciplines and trained lay persons on a continuously available basis, hospice tempers the patient and family's experience of the difficult final period of life.

**Nonproprietary Name**
**and Trademark of Drug**

Prochlorperazine—*Compazine*
Diazepam—*Valium*
Chlordiazepoxide hydrochloride—*Librium*

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# The Spiralling Costs of Medical Care

## Is Medical Technology the Villain?

(First of Two Parts)

HERBERT H. HYMAN, PH.D.

A few short years ago, a poll was taken of New York City residents, in which they were asked to rank the major problems that concerned them. Only 5% of those surveyed cited health care issues as major problems. Crime, dirty streets, unemployment and noise ran well ahead of health-related problems. Things have changed since that early 1970 poll. The cost of medical care has come to concern more and more people. Hospital costs have become the number one inflation-related concern of the Carter administration. We hear about the 1000% increase in the cost of a day of hospital care over the last 25 years, the 100% increase of the last five years.[1] We hear about the 9% cap President Carter wants placed on the total increases in health care for 1979/1980. We hear about union workers wanting more take-home pay and fewer deductions taken out for their medical care fringe benefits. We hear about the extraordinary costs of the new radiology equipment, the CAT Scanners—$400,000 to $600,000 to purchase and half that amount again to maintain them annually. We hear about the great emphasis Health System Agencies place on cost containment and the standards recently promulgated by HEW to limit the number of beds, expensive medical procedures, and equipment. And we all hear from our neighbors about the out-of-pocket costs they must pay for drugs, physician fees, and dental care. In brief, the high cost of medical care is beginning to have its impact on an ever widening circle of Americans and they are letting their Congressmen/women know about it.

Although all of the components of medical care are rising in cost, it is the cost of hospitalization that is going up most quickly. And it is usually the hospital which has the financial capacity to purchase expensive equipment and hire highly paid physicians and technologists to operate this equipment. Consequently, a brief examination of the trends in hospital costs is essential. Hospital costs are traditionally divided into two segments, labor and non-labor. In 1955, labor amounted to 62% of the costs of a hospital day of care. Non-labor (which includes the medical technology which interests us in this paper) costs were 38%. By 1969, labor component was reduced to 59%. By 1975, it was reduced to 53%.[2] In brief, the medical equipment and other non-labor costs were rising far more rapidly than the costs of labor. This, in spite of the fact that the increase in hospital workers' wages increased more quickly than the average wage of all other industries. Thus, at first glance we can state that medical technology and our love affair with it may well be the villain in the rapidly escalating costs of medical care. But, before we jump to that conclusion it is necessary to examine the historical background that led to this marriage between the hospital and medical technology.

### How It Happened

Starting with the Great Depression of the 1920's and continuing into the end of World War II, there were either no funds to build new hospitals or there was no construction materials available to build them because the war effort held first claim. Thus, for a period of almost 20 years little or no building of new hospitals took place. Following World War II and continuing for several years into the early 1950's, there was a huge backlog of consumer demands for public works, particularly roads and sewer systems, and for public necessities such as schools and hospitals. In this period of expanding the nation's store of capital goods and of refurbishing industrial

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plants and buildings of the United States, three significant occurrences, two in the health field and one in foreign relations, profoundly affected and set the course for our love affair with technology.

First, the Hill-Burton Act was passed in 1946 to assist small communities and especially rural communities to build community hospitals and facilities which would attract physicians. In the next 30 years, some $15 billion dollars were spent on hospital expansion with the federal government supplying one-third of it under matching formulas.[3] These buildings required the latest equipment commensurate with the level of modern treatment they intended to be provided to patients. This bill thus was major impetus for the hospital equipment industry and hospital suppliers to develop newer, more efficient and consequently more costly ways of treating patients.

Second, the governmentally funded National Institutes of Health, which began in 1938 with the establishment of the National Cancer Institute, experienced major growth from the 1950's and until the mid-1970's when a brake was put on increasing their expenditures. The original institute concerned with cancer grew to include ten different disease entities at a cost of more than $14 billion dollars over the last 20 years. This huge sum of money was spent solely on medical research with the great medical schools of New York City alone receiving about 10% of the funds. This emphasis on medical research in our medical schools and teaching hospitals fostered the specialties and super-specialties with which we are so familiar today. Federal money spawned a nation of medical scientists for whom the practice of medicine was secondary to research and teaching. Newly educated physicians learned about the marvels of the new technology which were issuing from the medical suppliers as well as about the research undertaken by their colleagues in medical institutions.

Third, an international space race was touched off by Russia's sending a rocket into orbit, a coup which was followed by a declaration of President Kennedy and Congress to beat the Russians to the moon. The billions of dollars which were poured into this effort led to the application of existing technology to space vehicles and to the development of new technology to monitor the astronauts' health. Some of these new inventions were directly applicable to advancing the medical technologies used in treating patients. Laser beams were applied to the treatment of cancer, and computers and electronic equipment led to the development of the new CAT Scanners.

While there are many other factors that led to the fantastic growth of technology and its application to diagnosis and treatment of patients, these three are to me the most significant. They have directly and indirectly spurred the initial increase in medical technology and research and helped to maintain its growth.

**American public demands the best:** The emphasis placed on medical technology also has been blessed by the average American. Progress in the United States has always been associated with material advances and the invention of new gadgets. Americans quickly grow tired of their possessions and demand new fashions, fixtures, equipment, utensils, accessories, homes, cars and entertainment. This demand for the latest carries over to the physician's office and to the hospital. Americans are aware of the new buildings, the new equipment, the increased number of staff when they enter a hospital. And they are willing to pay for these improvements.

However, it is the way they pay for these costs that make them immune to the real costs of service. They have sacrificed higher take-home pay for increased medical benefits. Because employees always received a real pay increase along with an increase in their fringe benefits they have not looked upon the higher costs of fringe benefits as a sacrifice. Secondly, the insurance industry's development of the major medical concept has further reduced the strain on a person's savings in the event of a catastrophic illness. The combination of the insurers' paying the first dollar costs for 90% to 95% of a short hospital stay plus major medical coverage for serious or prolonged illness has cushioned the average American from the brunt of major health care expenses. When one adds to this the insurance which substitutes for lost pay due to illness, the average American is almost immune from paying or feeling the economic impact of high cost hospital expenses. This fact is borne out in a study of the net cost of hospital care to the consumer over a 25-year period.[4] That study clearly shows that the amount a person paid out of his own pocket in 1950 for a day of hospital care was $7.75 or 50% of the total cost. (The rest being paid by government or medical insurance.) By 1975, the patient paid $18.03, but insurance paid $133 of the average $151/day cost. This 1975 out-of-pocket cost represents only 12% of the hospital bill, a great reduction from 1950. But, even more amazing is that the part of his spendable income that was spent on hospital care hardly changed at all between 1950 and 1975. In 1950, the average worker spent 19% of his/her income on hospital care and in 1975, it had increased to only 22%. In sum, the worker hardly feels the dramatically increased cost of hospital care as a special economic burden.

But the low economic cost to the worker may not be the most important factor associated with his/her acceptance of rapidly increasing hospital costs. Regardless of differences in income and expenditure patterns, the average American emulates the rich. By sacrificing small amounts of take-home pay for medical insurance benefits, Americans can feel on a par with the wealthy when it comes to obtaining medical treatment in the hospital. Having paid their dues with medical insurance, they demand the best care. If they feel cheated or neglected in their efforts to secure this high quality care, they are quick to strike back at the physician or hospital with costly malpractice suits, or vociferous complaints about the service received from the medical provider. The public wants to be treated the way the provider will treat the wealthy, and this means the use of expensive medical procedures, regardless of cost.

Probably the most important factor, however, is the average American's great faith in the capacity of American technology to cure illness. Consumers want medical science and the technological equipment developed by it to extend their lives, to improve their capacity to function in a relatively normal manner, and to reduce or eliminate pain associated with illness or disease. And they want this at little or no economic, psychological, physical, or social cost to themselves. The patient wants a personal miracle through the use of our latest technological advances. This belief in the miracles of medical science is strong in Americans in spite of the evidence to the contrary. Colman has stated:

> "Positive health can be achieved only through intelligent effort on the part of each individual. Absent that effort, health professionals can only insulate the individual from the more catastrophic results of his ignorance, self-indulgence, or lack of motivation."

Victor Fuchs seriously doubts that the spread of medical technology has contributed much to the health of Americans or that its future expansion would make much difference.[6] However, the facts are not as important to the consumer as his own perceptions of what medical technology can do for him/her in time of serious illness.

**Physician education:** In 1972, there were 320,000 active physicians. Of these, 250,000 or 78% worked in a specialty area. Since 1954, there has been a steady increase in medical schools, from 81 in 1954 to 108 in 1971. Along with this increase has been a larger number of graduates from 7,000 in 1954 to 10,000 in 1972.[7] In 1972, 87% of the residency positions available were filled. Only one category deviated greatly from that average. Only 60% of the general practice residency positions were filled.[8] Surgery, internal medicine, pediatrics, radiology and so forth had little difficulty filling the great majority of their positions. What do these isolated bits of data tell us?

First, that American doctors are a product of their society. Since society places a higher premium on specialization, the great majority of medical students specialize when they enter practice. Specialization is intimately related to learning how to master and use the medical technology associated with that speciality. Therefore, both in medical school and later in their residencies, our future physicians become familiar with and comfortable in handling ever more exotic equipment. Many of them become enough fascinated by this technology that they are readily lured into medical research using the billions of dollars poured into the medical schools and teaching hospitals by the National Institutes of Health and large private foundations (Rockefeller, Johnson, Kellogg). Articles relating their discoveries pour forth by the thousands each year. The best practitioners and researchers become much sought after as faculty members and chiefs of staff in their specialty. The government and foundations provide more research funds to these eminent men of medical science. Suppliers court their favor and sell them the latest equipment to use in their experiments or their treatment of patients. They, in turn, teach their students the complexities of diagnosis and treatment equipment. Upon graduation and after fulfilling their residency requirements, these newly indoctrinated physicians desire to practice only where they have access to this technology. It gives them power, influence, status and promise of high income. It is therefore not surprising that they gravitate to the urban and suburban centers where most of the large, prestigious medical schools and teaching hospitals are located. The small community hospital and the rural clinics are just too small and isolated from the medicine they learned and the colleagues with whom they desire to be associated. And the American public is satisfied for them to be located in the populous urban centers and suburbs where most live. The tendency of the health care system to emphasize these more sophisticated elements of diagnosis and treatment has been referred to as the "technological imperative."[9] Compared to the mundane practice of family medicine with its treatment of common, usually self-curing ailments, a medical practice associated with complex equipment and elaborate facilities in a prestige hospital is considered the only true way to practice medicine. As long as the American public perceives that the prolongation of life span is inextricably linked to treatment by medical specialists manning a battery of sophisticated machines, physicians will be trained and educated to satisfy this need.

**Explosion in medical technologists:** In spite of the physicians' medical education, they could not possibly operate and maintain this sophisticated equipment without a whole array of allied medical support technologists. Just as there has been an expansion of medical schools so too have there been the birth and expansion of many training programs for the technologist. A list of these changes will illustrate the growth of these numerous sub-specialty technical positions:

*Practical nurse training:* 16,500 graduates in 1960 and 44,000 in 1972.

*Physical therapists:* 682 graduates in 1961 and 2300 in 1973.

*Radiologic technology:* 2300 graduates in 1962 and 6300 in 1973.

*Respiratory Therapy:* 48 graduates in 1964 and 900 in 1973.

*Musical Therapy:* 18 graduates in 1962 and 140 in 1973.

*Speech Pathology/Audiology:* 2250 graduates in 1961 and 9200 in 1973.

*Medical Record Administrators:* 137 in 1960 and 263 in 1972.

*Health and Vital Statistics:* 15,600 graduates in 1961 and 30,700 in 1971.

*Public Health Nutrition:* 33 graduates in 1960 and 123 in 1972.

*Dental Hygienists:* 1200 graduates in 1962 and 3400 in 1972.

*Cytotechnologists:* 290 graduates in 1963 and 427 in 1971.

In addition, there are programs in biomedical engineering, automatic data processing, economic research in health, orthotic and prosthetic technology, and specialized rehabilitation services.[10] A quick examination of the statistics shows that there has been from two- to ten-fold or more increase in graduates produced by these various degree programs. The physician who commands these growing resources of support specialists requires a first hand knowledge of what they do so he can properly supervise their work and order tests required for patients. As of 1974, the National Center for Health Statistics identified almost 100 specialties in the medical care field and the number keeps growing. Over 4.5 million workers are connected with these specialties, most of which did not exist 25 years ago. They are a product of our demand of high quality care based on specialization. The technologists, of course, become a force in their own right and are making their demands on the health care system for recognition and status. Any thought of changing the medical emphasis on technology would require dealing with this formidable force that has grown so rapidly in the last 15 years. While the explosion may have abated somewhat the last few years, its major growth has already occurred. And almost all such positions are wedded to sophisticated medical technologies and equipment.

**The Others: Hospital Trustees, Administrators and Insurance Companies:** The American competitive urge also infects the board rooms and the hospital administrator's office. Striving to be number one is infectious, especially if it is relatively costless. To lure physicians trained at the best medical schools, the hospital administrators must supply the space, equipment and ancillary personnel to meet the physician's needs. The board of trustees, usually business-oriented leaders themselves, are as much in tune with this competitive spirit as are their administrators. As long as most, if not all, the costs of medical technology are borne by governmental, non-profit, and commercial health insurors, then it becomes even more attractive to purchase the very best. Since the added costs of most of these new medical inventions are buried in the increased per diem costs, the incremental increases do not seem to point to any one medical technology as the cause of the increase in hospital care. No one asks or is even concerned with answering whether the new equipment makes a difference to the life, comfort and well-being of the patients or their families. The fact is that no one really knows the answer to such a question. For an individual patient, it is possible to offer a specific answer. How applicable that answer is to others undergoing the same treatment is unknown. The administrators and their boards are satisfied with their hospital additions, as are the physicians with the latest knowledge learned at the best medical schools and the equipment supplied for their use. The hospital's competitive position is maintained or improved.

Thus, we see that there are a number of interacting, but autonomous forces at work that encourage the use, experimentation, and continued diffusion of medical technology in our hospitals, clinics, and physicians' offices. There has been little reason to raise questions up to now about this trend and more reason to support it..

### Who Pays for the New Technology

There are four major sources of funds for meeting health expenditures: public financing, private/non-profit insurance companies, out-of-pocket expenses, and private philanthropy. All four sources directly and indirectly pay for the costs of introducing medical technology into the mainstream of health care. As one researcher has discovered, "the great majority of new technologies are introduced within the current reimbursement system." These reimbursement measures include Medicaid, Medicare, Blue Cross, and commercial insurance companies. This is done with the concurrence of the American public through support of Congressional actions respecting governmental medical programs and in the private sector through the support of increased health benefits negotiated in union contracts. It is only within recent years, as the workers have demanded higher take-home pay and Congress and the executive branch have been concerned with the escalating costs of this care, that greater attention has been paid health costs and particularly those associated with hospital care.

However, new costly experimental programs are not always reimbursed under third party contracts. Nonetheless, sources of funding are still quite available for experimentation. The largest source of these funds emanates from the national health institutes, going primarily to the large medical schools, teaching hospitals and specialized hospitals and laboratories, including universities. Supplementing these funds are special philanthropic grants from wealthy individuals or their endowed foundations. In many instances, even this new experimentation in time becomes accepted as normal and routine once findings have been reported in conferences and professional journals. As the individual medical technology spreads as accepted practice, oftentimes while it is still in its developmental stage, it becomes a part of the per diem operating costs which are subject to reimbursement from health care insurors. How it occurs that a new medical technology is transformed from excepted, non-reimbursable costs in some institutions to part of the per diem charges in other institutions where it has been adopted is still not well understood. Nevertheless, until very recently, the increased costs were sanctioned and eventually accepted as part of the hospital's cost of providing service.

### Economic Outcomes

An examination of the data available indicates that a number of factors have been responsible for the rapid increase of hospital costs. Among these are:

1. Increase in non-payroll expenses
2. Increase in payroll expenses
3. Inflation
4. Increase due to greater utilization, especially of short-stay acute care beds
5. Population growth

Of these five factors, the increases in payroll and non-payroll expenses accounted for almost 70% of the increase in costs between 1965 and 1973.[12] Adding inflation to these two factors they accounted for 90%. The two smallest factors are increased use and population growth. The increased costs due to payroll expenses are explained by a number of factors. The number of personnel per patient rose from 2.26 in 1960 to 3.15 in 1973, a 72% increase. With the swift dissemination of expensive and complex medical technology, the type of staff hired to operate these machines and equipment is more costly than heretofore. We earlier noted the rapid increase of a number of ancillary well trained staff to meet the operation and maintenance needs of the hospitals. Furthermore, this has been a period of rapid wage increases. Since hospital staff has traditionally been one of the lowest paid industries prior to the 1960's, with the advent of Medicaid and Medicare and the general acceptance by 3rd party insurors of rapidly increasing per diem rates which were passed onto the consumer, hospital workers not only caught up to the general earning levels of the average American worker, but have passed it and are slowly widening the gap in their favor.[13] There are thus more highly trained and better paid hospital personnel in 1975 than in 1965.

The non-payroll costs have risen even more rapidly than labor costs. From 1955 to 1975, labor costs have risen by 9% per year, whereas non-payroll costs have increased by 11%.[14] A recent study of 24 medical technological innovations shows that they have had differential impacts on several hospital indicators from 1960 to 1972.[15] There has been a decrease in the number of hospital days in 14 diseases treated by these innovations, some dramatically lower. For example, there were 950,000 fewer patient days for nephrotic syndrome in 1972 than in 1960; 365,000 fewer days for duodenal ulcers in the same time period; and 80,000 fewer days for acute nephritis. On the other hand, 12 of the diseases have witnessed increased hospital days, the most dramatic being arteriosclerosis by 1,000,000 days, cataracts by 725,000 days and osteoarthritis by 661,000 days. The same is true for hospital discharges per 100,000 persons and mean length of stay. There have been increases and decreases due to the innovations. However, with respect to physician visits and prescription drug use, there have been dramatic increases as on-going, follow-up treatment has generally been required to maintain close scrutiny of the patients who have been treated with these medical innovations. This study further shows that for 16 surgical-medical innovations used in 1970 the return on costs of 21 million dollars expended by the National Institutes of Health for biomedical research resulted in an estimated $2.8 billion dollars of benefits as measured by reduced mortality and a higher rate of returning to productive work. This is a benefit-cost ratio of 135:1. While this is truly an astounding cost-benefit ratio, the study notes that if all the costs, including training grants, continuing research, and construction costs were added, the benefit-cost ratio would be reduced to 1.7:1, still a positive finding. In short, while there has been a rise in medical technology costs, the benefit: cost ratio indicates that from an economic point of view there was a pay-off in the use of such innovations.

At the same time these benefits are costing the consumer in net costs relative to the prices of other goods and services less in 1974 than they did in 1950! Measured by the prices of 1967, the net cost of a day of hospital care was $10.75 in 1950 and only $10.23 in 1974.[16] This truly remarkable fact helps to account for the consumer's relative lack of interest in the rise in the costs of health care. For a lower net cost, consumers receive better care in new facilities which use the latest medical technology. How could there be a better bargain?

**The Cycle:** When one takes these various factors into account, it seems that the medical industry and hospitals in particular are simply being responsive to the demands of the consumer. Finding hospital care a bargain compared to other goods and services, the consumer demands more and better services and the physicians oblige by putting pressure on the hospitals to supply these newest medical innovations. Looked at in this way, there is really no one villain in the crowd, not the physician, nor the hospital, nor the consumers. All are part of a cycle, each putting pressure on the other to have their own best interests met. Because the cycle interrelates so well, it becomes difficult to know where to intervene at all. Yet, why is there a growing chorus at this time to hold down the escalating costs of hospital care, and medical technology in particular?

In Part II, we aim to explore the sources of the negative reaction to the growth of medical technology, governmental efforts to deal with it, and a three-pronged strategy involving medicine, the community, and the consumer to counter it.

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# The Medical Device Amendments of 1976—Panacea or Pox?

(First of Two Parts)

JAMES F. COARSE, M.S.

## Introduction

On May 28, 1975, President Gerald R. Ford signed into law the Medical Device Amendments of 1976.[1] This new statutory scheme, an amendment to the Federal Food Drug and Cosmetic Act, culminates a decade of efforts to provide safe and effective products for human use.

Medical devices have proliferated in number, sophistication, and in kind since the end of World War II. Over 5,000 different devices produced by more than 1,500 manufacturers are now in use in American hospitals.[2] Overall, biomedical instrumentation and equipment sales are expected to total 2.3 billion dollars by 1980.[3] Despite the rapid growth of the field there has been little regulation or standardization. This has been reflected in reports on malfunctioning apparatus. In a report published in 1972, 26 of 41 types of defibrillators were found to have understandardized energy levels; 56 of 95 patient monitors had excessive current leakage, and 75 percent of electrocardiographs tested had poor frequency response.[4] The American Medical Association publishes a journal entitled *The Citation* which lists suits brought by patients injured by malfunctioning apparatus, drugs and errant physicians. Despite the plethora of automated laboratory equipment, recent studies indicate that the clinical laboratory may be grossly inaccurate. In one study, only 20 laboratories out of a total of 225 in a state could produce acceptable results 90 percent of the time.[5]

The Medical Device Amendments of 1976 is probably the most significant federal legislation ever enacted regarding devices and diagnostic products. The 1976 amendments alter the operational arena for the medical device and diagnostic product industry, the Food and Drug Administration (FDA), health care providers, and the users of devices. The purpose of this paper is to assess the impact of this landmark piece of legislation in terms of its potential for solving some problems confronting the health care system and consumers, and its potential for creating other problems in the same area.

## The Medical Device Amendments of 1976

As enacted, the medical device bill amends S201 of the Federal Food, Drug and Cosmetic Act to include an official definition of "device."[6] The inclusion, regarded by industry as an essential part of the act, was the subject of debate for many months. In essence, "a device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is: 1) recognized in the official national Formulary, or the United States Pharmacopeia, or any supplement to them, 2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or in other animals, or 3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes." Thus, certain articles formerly regarded as "new drugs" will now be treated as "devices" and regulated under the Medical Device Act. (P.L. 94-295).

It establishes a classification system[7] of devices intended for human use into three categories based on the extent of regulation deemed necessary to assure safety and effectiveness. They are:

*Class I—General Controls*

Applies to those devices for which controls other than standard-setting and premarket approval are sufficient to assure safety and efficacy. It also applies

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to devices for which insufficient information exists to determine that general controls are insufficient, but do not pose an unreasonable risk of illness or injury. Devices in general controls, however, must meet certain requirements, such as registration, record and report-keeping, conformance with good manufacturing practices, quality control and adequate labeling for safe and effective use.

*Class II—Performance Standards*

Class II includes devices for which general controls are insufficient, but for which there is sufficient information available from the medical and scientific community to establish performance standards and for which performance standards are necessary to assure safety and efficacy. Performance standards include those for biocompatibility, material characteristics, electrical safety, device performance and energy emission levels.

*Class III—Premarket Approval*

Devices in the premarket approval category are classified as either life-supporting, life-sustaining or potentially hazardous to good health. In addition, sufficient information to establish a performance standard to assure safety and efficacy of the device is not available. If an existing standard is determined to be insufficient to control a device, that device would also be placed in the premarket approval category.

Section 513B[8] requires the Secretary of HEW to establish panels of experts to issue recommendations regarding classification (see previous section for detailed description panels). These panels[9] are composed of experts in medicine, engineering, biological and physical sciences. They must also include consumer and industry representatives. Each device is reviewed and a report and recommendation for classification is submitted to the Secretary (HEW). Recommendations are subsequently published in the Federal Register and no further action is taken until comments are received. This process may require a six-month waiting period.

Any device classified in Section III may be reclassified via a petition and review process[10] initiated by the FDA or an interested person. The FDA must reclassify the device or deny the petition within 180 days after filing.

One extremely important provision of the new law involves the concept of product development protocol.[11] Designed as an alternative to the premarket application process, the sponsor submits a protocol to the FDA prior to testing. If the FDA approves the protocol, the sponsor can proceed with testing the product, being relatively assured that the product can be marketed upon demonstration of satisfactory results to the FDA. If the device is modified significantly after marketing, the same protocol can be repeated; but, the manufacturer *may* have to repeat only a portion of the study. This procedure saves the time and expense of developing a new protocol everytime there is a change in the device. The general purpose of the product development is to establish some abbreviated method for processing devices through premarket clearance.

Under the law, the FDA may authorize federal agencies and/or private business firms to develop performance standards for Class II devices.[12] To date, the FDA has encouraged the development of private standards. Recommendations for adoption of performance standards are submitted to advisory committees established by the Secretary of HEW. If accepted, these standards become departmental regulations. The review panels are not the same panels which review and classify devices mentioned above.

All devices, regardless of classification, will be subject to general controls of the Act. These include the requirements of truth in labeling and adequate directions for use.[13] All devices will have to be manufactured pursuant to Good Manufacturing Practices (GMP's).[14] GMP's for the medical device industry will be essentially the same as those required in the pharmaceutical industry. These regulations not only pertain to the manufacture, but also packaging, storage and installation of devices. Manufacturers will also be subjected to factory inspections which are far more extensive than those that have heretofore been employed for devices.

The new act also imposes record-keeping requirements in addition to those required by GMP's.[15] These regulations ostensibly limit record-keeping requirements to those which the Secretary of HEW may reasonably require to carry out his duties with the provision that the regulations not be unduly burdensome.

The bill also provides for notification of risks of substantial harm, along with repair, replacement or refund[16] of purchase price. If the FDA determines a device presents an unreasonable risk of substantial harm to the patient, the manufacturer is required to notify all users of the device of the potential harm.[17] Notification of risk would go to the person exposed, unless the notification poses a greater danger than lack of notification, in which case the prescriber must be notified. In such cases, the prescriber may be ordered to contact the patient and general disclosure is made through the news media after the potential hazard has been eliminated.

In addition to notifying the user, the manufacturer may be required to repair the device to eliminate the defect and, if that cannot be accomplished, be required to replace the device with an equivalent product, or refund the full purchase price, provided the device has been owned for less than one year.[18] A reasonable allowance may be refunded if the device has been owned for more than one year. This provision can be enforced only if there are reasonable grounds to believe that the device has not been mistreated by the user.

P.L. 94-295 also allows a physician to order a "custom" device for his own use or for his patients as long as that device is not generally made available by the manufacturer.[19] The law also contains provisions regulating investigational devices including requirements for informed consent of subjects and approval of protocols by institutional review committees established to protect the safety and welfare of research subjects and patients.[20]

Under the provisions of Section 516, the agency may ban any device, after consultation with an appropriate panel, found to present a substantial deception or an unreasonable and substantial risk of illness or injury that could not be eliminated by a labeling change.[21] Banning would be imposed through the publication of a notice of proposed rules-making, the invitation and consideration of comments and issuance of a final regulation. In the case of urgency, a ban may be made effective on the date of publication of the notice of proposed rule-making, with opportunity for an informal hearing to follow.

Unlike the pharmaceutical industry, many medical device manufacturers are small businesses. Acknowledging the substantial contributions that these manufacturers have contributed to the advancement of medical care, the law empowers the Secretary to establish an office in the Department of Health, Education and Welfare to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with provisions of the new act.[22]

### The Food and Drug Administration—Its Responsibilities

The Medical Device Amendments of 1976 embody many activities that already were in practice, both through the FDA and voluntarily through the medical device industry and health care providers. It also includes many activities adapted from regulations affecting the pharmaceutical industry. Industry and Congress recognized shortcomings in the Food, Drug and Cosmetics Act and eventually agreed that the act needed specific amendments in order to clarify the FDA's authority over devices and to differentiate device regulation from drug regulation.

In essence the new law means that whereas the FDA could formerly remove a medical device from the market only after harm had been demonstrated, now it has the responsibility for preventing the dangers associated with the use of any device before any harm can occur. Under provision of the act, the burden of proof has shifted from the FDA to the manufacturer. Public Law 94-295 significantly strengthens the FDA's control over medical devices.

It is now incumbent on the FDA to implement the law through the promulgation of regulations. Success of the law is largely dependent on the manner in which it is administered and regulations promulgated. The FDA must conscientiously work with industry and health-care providers to achieve the purpose of the amendments without over-regulation. Unsafe products are obstacles to good health care, but so too are escalating costs and the inability of a system to innovate and improve products. Excessive regulation could aggravate the rising price problem and stifle innovation.

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# The Problem of Poisoning

ALEX A. CARDONI, M.S.

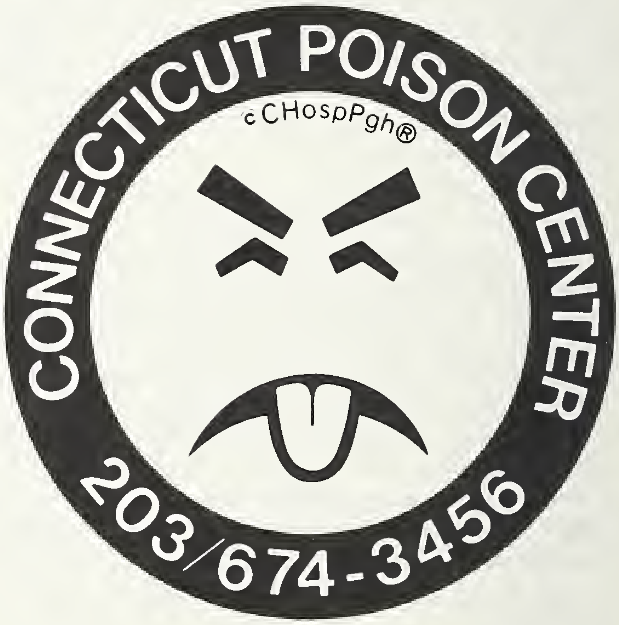
What is a poison? What is a poison center? What should people do if they suspect that they or a relative or friend have been poisoned? How can accidental poisonings be prevented?

These questions appear to have simple answers. Or do they? Fiction and history are filled with reference to poisons. Snow White, Romeo and Juliet, Socrates, the Medici's and Borgia's of Italy, and on and on. But these were intentional poisonings. Most of the poisonings that occur today are tragic accidents occurring in children under the age of 5. Why do they happen?

Young children do not know what "poison" means. Many adults fail to identify the familiar products they use every day as potential poisons. Most adults think of a poison as an "ugly"—cyanide, arsenic, lead. In reality most poisons causing problems are "sweeties"—things that make us look and feel better and make life easier. Items such as cosmetics, room sprays, cleaning agents, and other household items. If adults fail to recognize poisons in the home, how can they educate their children to stay away from them. For years, the medical community has been urging parents to lock up poisons but if adults do not know what poisons are, how can they lock them up? How do you lock up a toxic plant? Even with adult recognition of poisons in the home and with efforts to keep them locked up, poisoning data indicate that about 85% of accidental poisonings occur while a product is in use. Thus, while locking up poisons is desirable, in some cases it is impossible. In addition, it cannot prevent the accidental poisoning by a product in use.

Another situation which contributes to the problem of accidental poisoning is that adults do not understand how children under 5 perceive poisons. Children of this age group think that poisoning is something that one person does to another, but not as something that they can do to themselves, e.g. the wicked witch poisoned Snow White. Children also emulate adult behavior. When they see mom or dad liberally spraying a room with air freshener they will do the same thing. The problem is that they could spray it directly into their eye.

The nature of packaging of these "sweeties" attracts the child under 5. Most are packaged in bright colors and some have animated characters on the labels. Children of this age cannot read so caution statements and warnings have no meaning to them.



For years we have been citing children's curiosity as a reason for accidental poisoning. But we too easily forget that children are often hungry and thirsty. When was the last time you asked your pre-schoolers if they were thirsty? Children of this age are always asking for drinks. This is especially a problem just

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before lunch and dinner-times when mom is busiest and giving least attention to her toddlers. The combination of a thirsty child, a bright-colored lemon flavored cleaning solution, and a busy mom can lead to tragedy.

A child's concept of poison is primitive. Children under 5 think of poisons as solids, have little understanding of liquid, and no concept of aerosols or invisible poisons (carbon monoxide). They think that all poisons enter the body through the mouth, except poison ivy and snakebites.

These are some of the reasons why 80% of an estimated 4.5 million annual poisonings in the United States occur in children under the age of 5. Children are poisoned because adults do not know what a poison is. Children are taught not to play with knives, razors, and electrical outlets, and generally these are not a problem in the average household. But children are not taught to avoid poisons because adults do not know what a poison is.

Most adults do not know what a poison center is. Their concept of "poison center" is a place where antidotes are available to treat poisoned victims. In contrast, a poison center is *information* and *people* who are expert in dealing with poison emergencies. Antidotes exist for only very few poisons—the "uglies"—arsenic, lead, cyanide. Most poison emergencies are handled without the use of specific antidotes. The Connecticut Poison Center in Farmington has the largest collection of information on the composition of hundreds of thousands of commercially-available products. In addition, we have a number of consultants who specialize in different types of poisonings that we can call upon for assistance when needed. We have 3 full-time and 12 part-time professionals who advise the lay public and health professionals on poisoning. We have a commitment to education and to continued research which insures that the Connecticut Poison Center will keep abreast with the latest developments in the field of clinical toxicology.

How can accidental poisonings be prevented in children under 5? We believe that use of the Mr. Yuk warning symbol will significantly reduce the number of accidental poisonings in children of this age. Mr. Yuk is green and mean, but he could save a life. His message to the pre-schooler who cannot read is *NO! Do Not Touch, Eat, or Drink*. Children can be taught the meaning of Mr. Yuk and not to touch any container that carries a Mr. Yuk warning symbol. Parents and children working together to identify and label all poisons in the home can make it a safer place to live. If something does happen, the telephone number of the Connecticut Poison Center is immediately available to seek advice on what to do.

In February the Poison Center formally introduced Mr. Yuk to the citizens of Connecticut. Over the next 6 months, the message of the problem of poisoning and how to prevent it will be carried to all families in Connecticut via television, radio, and newspaper. In addition, the Connecticut State Federation of Women's Clubs, Inc. will help us distribute Mr. Yuk stickers as they speak to adult groups about poisoning.

Complex problems do not have easy solutions. The problem of accidental poisoning lies not with the curious child but with the uneducated adult. The solution to the problem is found in increasing adult awareness of what a poison is, how children perceive poisons, what a poison center is and what to do in case of poisoning.

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# Negotiation—A New Dimension in AMA Activity

SEYMOUR J. BURROWS

Like it or not, the American physician must become more adept at developing accord with his peers, his patients, his hospitals, and all those outside parties who ever more frequently impact upon his profession. An ability to negotiate will be required, either as an individual or as a member of a group. The time when a physician could immerse himself in his practice and remain incognizant of the outside world has passed. "The old order changeth, yielding place to new."

To meet this perceived need, the American Medical Association, at its Interim Meeting in December, 1975, created a Department of Negotiations. This department was established by the AMA . . . "to direct and coordinate a joint undertaking with constituent and component societies to provide consultation and representation where needed on behalf of members, individually or collectively, with respect to grievances, disputes, professional problems, or terms or conditions of employment by hospitals or privileges in the case of attending physicians who are not hospital employees."

And, recognizing the problems of residents, the House of Delegates at the same time took the position that . . . "it is appropriate for constituent and component societies to aid, assist or represent interns and residents individually and collectively in resolving disputes with hospitals. Such activities should be geared to achieve legitimate objectives without sacrificing the quality of graduate medical education or patient care."

Under these directives, the Department of Negotiations established a three-pronged program. First, to advance knowledge of both the techniques of the negotiations process and the availability of the department, seminars and institutes are being offered to members of the AMA and to medical society staff executives. To supplement the training received in these meetings, participants receive *Negotiations Update,* an irregular periodical that keeps them up to date on negotiations affecting the profession. Second, to assist physicians and the constituent and component societies with problems where a negotiations interface exists, to consult and advise upon request. Third, to work with constituent and the larger component societies to establish negotiating structures that will serve as a base for both continuing areas requiring negotiation and timely problems as they arise. Negotiating structures are presently active in Michigan, California, Washington, Texas, Colorado, and Florida, and are being studied in other states.

The decision of the House of Delegates was reaffirmed at the Annual Convention of the AMA in June, 1978, when, in adopting a report of the Board of Trustees, it stated . . . "The Department of Negotiations has been established to provide training, guidance, and counselling to medical societies and physicians in the alternative means of resolving disputes. Training programs are directed toward residents and employed physicians specifically, in addition to physicians and society executives generally. In implementing Board Reports U and Y, adopted by the House of Delegates at the 1975 Clinical Convention, the Department of Negotiations, in conjunction with local medical societies, has provided advice and consultation to physicians in such matters as individual due process, hospital-medical staff bylaws, physician group service contracts, etc. Moreover, the department has helped several state societies develop means of assisting or representing residents and other physicians in disputes and in dealing with the situations contemplated by the resolution. . . ."

The training seminars and institutes have been programmed on a regional basis, and have been open to physicians and society executives. Training sessions

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have also been cosponsored with state, county, metropolitan and specialty societies for the specific needs of their memberships. Cosponsored meetings, for example, have been held with the medical societies of Delaware, Wisconsin, Maine, Ohio, Iowa, Indiana, Virginia, and Arizona; Harris County, Texas; Chicago Medical Society, San Diego Medical Society, and Los Angeles County Medical Association; and with the California Plastic Surgeons, the College of Emergency Physicians, the College of American Pathologists, the American Association of Medical Society Executives, the Resident Physician Section of the AMA, the American Society of Plastic and Reconstructive Surgeons, and the American Society of Internal Medicine, among others.

The seminars and institutes begin with an introduction to, and an explanation of, the process of conflict resolution. Emphasis is placed on negotiating preparation, on group goals, strategies, flexibility through development of alternatives, and personality accommodation. Attendance is deliberately limited so that attendees can be assigned to teams and given negotiating situations to role play. The practical application of principles and procedures, having been acted out by attendees, are then specifically critiqued by department staff members. Physicians and society executives who attend the introductory seminars and institutes are invited to attend advanced sessions where, beside a review of the negotiating process, they learn how these principles are being practiced around the country, and engage in several mock negotiations that are based upon cases the Department has been in consultation. And, as a means of opening communications between society negotiating teams and those medical society leaders with responsibility for negotiating with HSAs and other government agencies, insurors, hospital governing boards and other third parties involved in the health care delivery system, the Department holds Invitational Conferences that, by a series of round-table discussions familiarizes the invitees with problems, disputes and their resolution that may face other professionals throughout the country, and offers opportunities to exchange ideas.

As a result of this spread of knowledge and availability of the Department of Negotiations' consultative services, the utilization and participation of their members who have attended the seminars by societies with problem solving and negotiating situations, has increased. In line with the third part of the department's mission, societies, as noted previously, have established negotiating committees or have cadres for ad hoc negotiating situations. With practice, as in any field of endeavor, skills and abilities are being honed.

The facts must be faced. No longer, in an era when governments and industries have become the bankrollers for all types of health services, can the medical professionals avoid form-filling and the influence of bureaucratic regulation. Coordinated efforts by the profession, for reasonable goals that can be achieved, will become the need of the profession. The time for internecine disagreement, for public or private vocalization, is during the group's goal setting. After that, you, we, cannot afford the luxury of a proud independence. Once set, the negotiators must be able to pursue those goals *within the parameters set by their peers* to the best of their abilities.

What is there to negotiate about? Many things. If you look at your own practice from a neutral position, you will realize that you are resolving many actual and potential disputes daily. State societies, apart from their legislative negotiating responsibilities, may be negotiating with hospitals and for hospital associations, HSA's, PSRO's, government agencies, insurance companies and others. Component societies may be negotiating with HSA's, HMO's, hospitals, public interest groups, and many others. Physicians, alone or in groups, are bargaining with employees and/or employee groups, serving on hospital committees, boards and various commissions which require negotiating abilities. Medical academicians and other salaried physicians are also in negotiating situations with their administrations and people under their supervision.

The fact that some group or institution is willing to sit across the table to discuss a situation and work for solution of a particular problem means they need what the societies and physicians represent. The problem—and the solution—lies within ourselves. The problem, that of intra-society and/or intra-profession negotiations, and ironing out the differences between ourselves before meeting with whatever opponent, has been the curse hanging over physician negotiations thus far.

Where are the opportunities for negotiation? They exist almost everywhere you look within the medical profession. Start with the new doctors, the residents. Within each teaching institution there exist administration-resident problems that can best be resolved through negotiation and agreement. Then, there are the problems that exist in many hospitals, between the physicians, administrations, and other staff. Bylaws, due process, personal contracts and working conditions easily come to mind. Relationships between physicians and the various insurors are subject to negotiations. And, you can undoubtedly name many more.

Why negotiate? First, the time for withdrawal from conflict as the easy way out of a situation has passed. If medicine is to continue serving its patients with improving quality care, the opportunity to so continue must be fought for. In spite of what appears to be vastly different views and objectives in the administration of health services (i.e., quality care vs. cost containment), there are common interests between the bureaucrats of government and the insurance companies (or, perhaps put another way, between the users of medicine's services) and the providers of health care. It is these common interests that negotiations seek, and with patience, find. The goals of both sides are not necessarily adversarial, if the similarities of their values are sought and discovered across the bargaining table. And those values are quality care for the greatest number within the abilities of either party to deliver. In essence, negotiations is the process of reconciling ideas, hopes, and values—what we involved in the process call "win/win." Meeting and openly discussing issues without trickery, deceit or abuse of power results in productive negotiations.

Besides bringing the message of negotiation to the membership through its seminars and institutes, the AMA Department of Negotiations has been active in a variety of consultations. It has worked with state society negotiating teams to develop research and strategies in state situations where, by law, the societies have had to negotiate in areas such as workers' compensation, Medicaid and other administrative functions. It has worked with employed physician groups (HMO's) in organization and contract negotiations. It has worked with resident groups in organization and contract negotiations. A developing area is group practice, where the hospital employee unions, ever alert for more dues income, are beginning to organize, and group administrators require assistance. Due process, refused or improperly handled by administrations in a variety of situations, have been brought to the Department's attention, and in many cases helped. Individual contract negotiations of hospital-based physicians have been set aright. And there is more.

The Department's consulting services are available to individual physicians and groups as well as to the state, county and specialty societies. Requests for consultation or advice can be made either formally or informally, by letter or telephone. In the cases of individuals or groups, they will first be asked if the problem or situation has been referred to their county or state society. If it has not, and further consultation will be required, they will be asked to see if either of those societies can be of assistance. If assistance is not available or forthcoming, they should then get society approval to have the Department of Negotiations work with them. Due process problems are a case in point. Where ignored, refused or sidetracked, the Department, acting in a mediator capacity, has been able to get the full due process outlined in bylaws followed by getting the opposing parties to sit together and work things out. The only request made by the Department to persons seeking its assistance is that their call for help be timely. Situations delayed too long may not be amenable to constructive assistance if specified time limits for action are allowed to lapse.

With the politicalization of medicine by legislative fiat and the proliferation of bureaucracies to administer those fiats, we appear to be faced with a strange attitude that seems to be percolating in regulatory agencies. That apparent attitude seems to be that their function, in addition to administering the laws, is to penalize any group that receives the respect of people who are helped because that group has functioned efficiently by delivering and improving quality health care and mental attitudes for patients. Success and respect of themselves seem to have become the criteria for penalizing the providers of health care while playing ostrich on bureaucratic mistakes and inefficiencies. That apparent attitude, coupled with the indiscriminate promising of benefits and results by both politicians and labor-management negotiators, while restricting the ability of providers to deliver services through restricted budgets without consulting or negotiating with the providers of that service present a present and future for negotiations.

The opportunity to learn more about negotiations, how it works and how it can help you will be presented several times this year. Introductory seminars this year have been held in Chicago (March 29-April 1), New York City (May 3-6). The next Introductory Negotiations Seminar will be held in Portsmouth, New Hampshire (August 28-31). A special Seminar on Negotiations for Employed Physicians will be held in Denver, Colorado (August 9-11). Details are available from Ike Mayeda, AMA Department of Negotiations, 535 North Dearborn Street, Chicago, Illinois 60610. J. Paige Clousson, Director of the Department of Negotiations, can be reached at that address, or at (312) 751-6652 for questions on how the Department may assist you.

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**ADVERSE REACTIONS**: *Cardiovascular*: Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. *Central Nervous System*: Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache, rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. *Gastrointestinal*: Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic*: Urticaria, rash, ecchymosis, erythema. *Endocrine*: Impotence, changes in libido, gynecomastia, menstrual upset. *Hematopoietic System*: Bone marrow depression, agranulocytosis, leukopenia. *Miscellaneous*: A variety of miscellaneous adverse reactions has been reported by physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.
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References: 1. Citations available on request — Medical Research Department, MERRELL RESEARCH CENTER, MERRELL-NATIONAL LABORATORIES, Cincinnati, Ohio 45215. 2. Hoekenga, M.T., O'Dillon, R.H., and Leyland, H.M.: A Comprehensive Review of Diethylpropion Hydrochloride. International Symposium on Central Mechanisms of Anorectic Drugs, Florence, Italy, Jan. 20-21, 1977.

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8-3921 (Y587A)

# Breast Cancer Screening: A Consensus Report

In 1973-74 Breast Cancer Detection Demonstration Projects (BCDDP) were initiated at 29 locations around the country under the auspices of the National Cancer Institute and the American Cancer Society. Their purpose was to demonstrate the feasibility of periodic screening of large numbers of women for breast cancer, using clinical history, physical examination, mammography, and thermography. Following inception of this program, however, questions were raised about the relative values of the screening components when compared to possible risks involved with the ionizing radiation from mammography. Critics suggested that the radiation used to detect cancers might also induce malignancies at a later date. No concern was expressed or intended regarding the obvious value and importance of *diagnostic* x-ray examination of the breast in women with signs and/or symptoms which might be related to breast cancer.

In October 1975, the National Cancer Institute appointed three experts to lead investigations into various aspects of these issues, by analysis of data generated by a study conducted by the Health Insurance Plan (HIP) of Greater New York, which began in 1963. A group headed by Dr. Lester Breslow of UCLA was to examine the benefits as determined by the HIP Study results; a group chaired by Dr. Arthur Upton, at the time Dean of Basic Sciences, Health Sciences Center, State University of New York, Stony Brook, was to consider and estimate radiation risks; and a group headed by Dr. Louis Thomas of NIH was to reexamine the pathology of cancers found in the HIP Study. Subsequently—in January 1977—a working group under Dr. Oliver Beahrs of the Mayo Clinic, was charged with reviewing in depth the findings generated by the BCDDP.

Recently, the National Institutes of Health and the National Cancer Institute convened a meeting, the NIH/NCI Consensus Development Meeting on Breast Cancer Screening, with the objective of developing a set of recommendations on the major issues and questions which have arisen concerning breast cancer screening and the BCDDP, including mammography.

The Panel appointed to deliberate on these issues met in open forum at NIH on September 14, 15, and 16, 1977, and reviewed the reports of the four study groups mentioned above, heard testimony from interested professionals, associations, BCDDP project directors, and members of the public. The questions, and a summary of the recommendations formulated by the Panel, follow. (Throughout its deliberations, the Panel repeatedly emphasized the distinction between mammography used for diagnosis—the value of which was not in question—and mammographic screening to detect possible disease in women who have no symptoms or physical findings whatsoever.)

### Question 1

Is there evidence that early detection of breast cancer leads to reduced mortality from breast cancer? Which of the available screening modalities or combination of modalities is most effective in early detection?

### Answer

The only sound scientific evidence which demonstrates a favorable benefit in breast cancer screening is derived from the HIP Study. The data from this randomized controlled trial—which formed the rationale and stimulus for the BCDDP—indicate that periodic breast cancer screening can decrease the number of deaths due to breast cancer by about 40% in women who are over 50 years of age. The age suggests that this may be related to menopause but the data in the HIP Study do not permit any definition of this question. However, the HIP Study thus far shows no decrease in breast cancer mortality attributable to screening women below the age of 50.

The evidence indicates that the benefit of the screening program rests on the use of physical examination and mammography, in combination. The Panel noted that there are no rigorous scientific data showing to what extent either physical examina-

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tion alone or mammography alone may be beneficial. The efficacy of physical examination as a screening procedure for breast cancer (e.g., by well-trained nurse practitioners) has not been examined.

The Panel acknowledged that mammographic techniques have improved markedly in recent years, with smaller, and presumably earlier, lesions now being detected. The advantage of mammography lies in the fact that appropriate therapy may be administered at an earlier stage of breast cancer, presumably improving prognosis.

Moreover, radiation dosage has been decreased significantly. Nonetheless, there are insufficient data to indicate that these advances have resulted in decreased mortality for women under age 50 at the time of screening.

**Question 2**

What are the risks of each of the available screening modalities for early detection of breast cancer?

**Answer**

Neither physical examination nor techniques such as thermography or ultrasound are known to have harmful effects upon the body. The use of mammography, however, is associated with an inherent risk of radiation exposure, and studies indicate that breast tissue is particularly susceptible to radiation damage.

The precise radiation risk is difficult to quantify, but current evidence strongly suggests that risk increases linearly with increasing dose and is linear down to the lowest dose.

At the present time, the average surface radiation exposure in the BCDDP centers is 1.2 (0.2 to 2.5) roentgens. It is estimated that every rad of exposure raises a woman's risk of breast cancer by about 1%. Thus, if a woman in the general population has about a 7% chance of developing breast cancer in her lifetime, one rad will increase her risk by 1% of 7%, or from 7% to 7.07%. The Panel observed that even with the cumulative dose that would result from a series of five yearly mammograms in the BCDDP—about 4 rads total with the newer techniques—the increased risk of breast cancer is so little that it could not be demonstrated in long-term follow-up studies of the BCDDP group.

With repeated examinations of one cohort of women, the likelihood of finding new cancers progressively declines after prevalent cancers are detected while the total radiation given each woman progressively rises. This puts an obvious limit on the advisability of repeated rescreening of the same population.

**Question 3**

Do the potential risks versus benefits differ for different methods of breast cancer detection and at different ages of patients screened?

**Answer**

The question of risk, in this context, applies only to mammography. Data from several studies indicate that the risk of radiation, in general, may decrease with age although data from the analysis of A-Bomb survivors show an excess of cancer in the age group over 50. Data suggest that the peak age of susceptibility is between 10 and 19 years and that the danger drops gradually thereafter. This possibility, too, argues for confining radiation, in this case mammography, to older age groups, but there is no conclusive evidence.

**Question 4**

If it is not possible to answer any or all of the foregoing questions, what data need to be generated to provide adequate answers?

**Answer**

New diagnostic/screening techniques are needed. The Panel recommended greater emphasis on research with noninvasive techniques, such as thermography, ultrasound, and biologic markers.

Because the potential benefits of thermography remain undocumented, the Panel recommended that thermography be discontinued as a routine part of the BCDDP screening program except in those centers where sufficient expertise is available to justify further clinical investigation and research. Because thermography in the BCDDP was not set up as a research study, its continued use should require the development of a research design.

The Panel deplored the lack of clear-cut data on the efficacy and the risk-benefit ratio of screening for women under 50, but they did not come to an agreement about the feasibility and logistics of randomized clinical trials to resolve such issues. However, clinical trials would be important in order to resolve certain questions concerning the efficacy of periodic breast screening.

The BCDDP should continue to monitor all women in whom breast cancer has been diagnosed. Although the Panel was unable to assess the feasibility of following all women who have had a mammogram in the BCDDP, there seemed to be general agreement that such followup would be important and that this question deserves further consideration.

**Question 5**

What are the practical and ethical considerations for implementing demonstration projects in cancer detection and how does the BCDDP comply with these considerations?

**Answer**

Demonstration programs by definition utilize proven and practical methods to project new information to the medical community. However, from its inception the BCDDP has of necessity incorporated certain practices of assumed but unconfirmed value.

As a demonstration program with investigational components, therefore, the BCDDP must come to grips with several important ethical concerns. The Panel recommended that the BCDDP's Informed Consent Form indicate the radiation dosage to be delivered to the patient, and assure that all information gained through the program will be disclosed to the screenee, as well as to her physician.

The Panel proposed that the screenee receive the Informed Consent Form and appropriate background materials beforehand, so that she would be able to discuss the proposed procedure with her family and her physician.

The Panel recommended that the histology of any lesion smaller than one centimeter in diameter, or any papillary or intraductal proliferation originally interpreted as malignant, be reviewed by at least two pathologists prior to definitive therapy.

Women who have been screened already and who have had a diagnosis of cancer should be notified promptly if there has been a change in diagnosis.

Any new experimental study should take into consideration a variety of issues, e.g., its justification from a cost-benefit point of view, the informed consent process, the way in which research subjects are selected, and the development of guidelines for compensation of individual participants who are injured in the course of the study. Furthermore, more women, both professional and consumer representatives, should be included in the design and planning of any future studies.

**Question 6**

What can the Consensus Panel recommend as to the type and frequency of breast cancer screening and who should provide the screening?

**Answer**

Based on the available evidence, with the understanding that no new participants are being added to the program and that limits be set on radiation exposure, the Panel recommended that BCDDP screening, using mammography and physical examination in combination, be continued for those women 50 and older who are currently enrolled. Regardless of the location for mammographic screening, upper limits should be set on radiation exposure consistent with best current data. Women subjected to mammography should ask for such information and should be urged to maintain their own personal exposure records.

The Panel found no convincing justification for routine mammographic screening for women under the age of 50. This does not imply, however, that physical examination and breast self-examination are not important for women of any age.

The Panel recommended that routine mammography for women 40 through 49 enrolled in the BCDDP be restricted to women having a personal history of breast cancer, or whose mothers or sisters have a history of breast cancer.

Mammographic screening for women below the age of 40 should be limited to those women having a personal history of breast cancer.

Ethical considerations, however, led the Panel to concede that women under 50 who are already participating in the BCDDP should be afforded the opportunity to continue having mammograms if they wish—so long as they are informed that there is no proven benefit and there is presumed risk, and that the Panel does not recommend screening mammography in this age group. (Again, the Panel went to great length to distinguish between mammographic screening and mammography used as a diagnostic tool. Thus, for example, if a woman under the age of 50 in the BCDDP develops symptoms or findings suggestive of breast cancer, she may well require mammographic examinations as part of her medical evaluation by her own physician.)

# Month in Washington

Unexpected Congressional pirouetting has made the chances of some form of a national catastrophic health insurance plan a distinct possibility in the immediate future—a possibility ruled out by most lawmakers earlier in the session.

The first domino to fall was the decision of President Carter to go with a first-stage catastrophic national health insurance plan in the face of strong opposition from organized labor and Sen. Edward Kennedy who seek a more comprehensive plan.

Then, Chairman Russell Long of the Senate Finance Committee introduced a significant modification of his long-standing catastrophic measure that gives private health insurance a much larger role and eliminates the controversial payroll tax feature.

At the same time, leading Republican Senators—Robert Dole, John Danforth, and Pete Domenici—offered their own, more limited catastrophic benefit approach.

As if a house of cards were falling, though the timing was coincidental, the Kennedy-Labor forces leaked their new NHI proposal, a sharply-scaled-back plan whose first phase looks a lot like catastrophic.

Many differences separate the various plans, especially in the area of controls, but the coalescing around the broad general theme of catastrophic of such divergent and once-hostile factions signals a new ball game on NHI and makes Congressional passage of a NHI plan by 1980 a possibility.

The great attraction of catastrophic is the low price tag, as little as $5 billion compared with the $30 billion and more cost of even the most modest comprehensive approach. And, from the political standpoint, there is undeniable voter appeal in the idea of protection against the costs of severe, prolonged illness or accident.

The dominant Congressional figure on catastrophic through the years has been Sen. Long, who with a few committee cohorts such as Sens. Herman Talmadge and Abraham Ribicoff, appeared to be waging a lonely battle against comprehensive plans backed by previous administrations and by Labor.

Everything is going Long's way this year. Carter's decision was a victory for him and a bitter pill for Kennedy. The support of Long's three Republican members on his Finance Committee for the catastrophic concept might forestall a partyline fight. The powerful lawmaker acts as if he's scenting a legislative triumph.

Long's new bill requires that employers provide catastrophic coverage. Wiped out is the provision in his previous bill—still before the Finance Committee—that would have financed this coverage through a one-percent payroll tax. The change pulls federal involvement several steps back and makes the measure far more palatable to private health insurers. Small businesses would receive tax breaks for providing this coverage and the self-employed would be entitled to a tax reduction.

Benefits in Long's plan would begin after $2,000 of physicians' bills and 60 days of hospitalization have been accrued. Long says he is considering lowering these levels.

The Dole-Danforth-Domenici bill also requires employers to offer catastrophic benefits through private health insurance with a "deductible" of $5,000 and 60 days of hospitalization. Employees would be free to choose whether to participate. The self-employed could purchase catastrophic policies that insurers would have to provide under agreements with the government. Medicare's coverage would be extended and liberalized. States would be required to provide catastrophic Medicaid benefits.

Long congratulated Dole for introducing the measure. He said, "I hope we can agree on something that would overwhelmingly muster votes on both sides of the aisle." Replied Dole: "I believe we have, along with the distinguished Senator's proposal, the basis of some agreement that might pass the Congress and that might help the American people."

* * * *

The NHI proposal slated to be unveiled soon by the Carter Administration is expected to call for a first phase program leaning heavily on the catastrophic benefit side.

Though many other features are contained in the Administration's plan, the initial key element is catastrophic. As a result, President Carter's plan will be viewed as part of a catastrophic triumvirate of bills on

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*Prepared by the Washington, D.C. Office of the American Medical Association.*

Capitol Hill, joining those by Sen. Long and Sen. Dole.

Not clear yet is whether the Administration will ask Congress to approve each of the projected five phases as a separate piece of legislation, or to enact the entire plan in one package.

At any rate, the first phase would mandate that employers provide workers with catastrophic coverage insurance with a $2,500 ceiling on out-of-pocket costs for an illness. The limit on Medicare hospital day coverage would be lifted and physicians would be required to accept assignment for Medicare patients. The federal government would pick up the tab for adding low income pregnant women and children to Medicaid where assignment also would be mandatory.

New hospital and physician cost control features are envisaged, and Health Maintenance Organizations would be encouraged.

In the next phase, a federally-established health insurance program called Healthcare would come into operation. This is designed to eventually supersede Medicare and Medicaid and to stand as a back-up health insurance plan to cover all not under private plans.

Under the plan, no federal expenditures would occur until 1983. This would provide time for Administrative planning; give initial cost controls and system reform incentives an opportunity to slow increases in health care costs prior to the expansion of coverage; and give employers an opportunity to plan for proposed standards on health insurance coverage for employees.

Physicians in all phases of the plan would be required to accept assignment for Medicare, Medicaid and Healthcare beneficiaries. A consolidated fee schedule would be established for all plans.

The Administration's hospital cost containment plan would be implemented in the first phase of the plan. After the completion of the last phase, alternative reimbursement plans linked to Gross National Product growth would take effect. A total expenditure limit system would be imposed.

* * * *

Sen. Edward Kennedy and his Labor allies have formally given up their long and vociferous battle for a federally-financed NHI program, bowing to the exigencies of budget-cutting and inflation.

Instead Kennedy is preparing to offer "a totally new approach" retaining private health insurance and financed largely by the private sector. The as yet unveiled plan is rumored to bristle with stringent federal controls—but is still a long way from the federally-run, federally-financed idea Kennedy launched 10 years ago.

The plan starts with the central concept first advanced by President Nixon of mandating employers to provide comprehensive health care insurance for their workers. A new and very controversial wrinkle is relating premiums to wages with the higher income people subsidizing the premium of lower income workers. Federal premium aid would be provided poor people and assistance would be given small companies financially hard hit by the mandate.

The second key idea, left over from the previous Kennedy-Labor plans, calls for a national health spending ceiling and establishment of federal and state budgeting and negotiating mechanisms for setting physicians' fees and regulating hospital costs.

There would be no cost sharing by patients and no limits on hospital or physician care.

All health insurers would be organized into four consortia which would bargain on a state or area-wide basis with health providers on prices.

Although the measure is designed to be approved as one package it could be phased in over a period of years. A likely first phase would be a catastrophic benefit.

* * * *

Hospitals reported costs in January were 14.4 percent higher than a year earlier due to general inflation, a higher birth rate and more surgery.

Paul Earle, Director of the Voluntary Effort, said double-digit inflation was making it difficult for hospitals to meet their voluntary goal of holding cost increases to 11.6 percent this year.

"Approximately two-thirds of the increase in expenses was a result of tremendous increases in general inflation, especially the cost of food and fuel," Earle said in a statement. In addition, he said, "The increase in births and surgical procedures was the greatest of any January increase in 16 years."

John Alexander McMahon, President of the American Hospital Association, told the House Commerce Health Subcommittee the Administration's hospital cost containment bill "would create a dilemma for hospitals because it would limit hospital spending while ignoring the causes of increasing costs."

Earle called the January figure "an interruption" in the general slowing of hospital expenses.

"Clearly hospitals are doing a good job controlling the expenditures they can," he said, "but they can't control the cost of food and fuel nor the number of people who get sick or the number of births."

Meanwhile, the AMA warned Congress that the consequences of error in the Administration's hospital cost containment policy "will be far greater than higher prices at the gas pump or the department store."

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# The President's Page

One of the interesting facets of becoming a spokesperson for organized medicine is the requirement that one reply almost on a daily basis to innumerable inquiries about our profession.

Often these questions are presented as challenges rather than as a true search for information and often they are meant to be a method of confrontation instead of a source of illumination.

Some of the old chestnuts such as, "When are you doctors going to permit more medical schools to open?" are really easy to cope with. Our record of support for medical education is documented for at least three decades. The end result (an increase in physician population) is documentable and is acknowledged by all who keep an open mind to information available to anyone. In fact, recently the attempt by government to limit the number of physicians as a method for reducing health care costs has received considerable publicity. The public is awakening to the fact that federal power is being used to attempt to control not only the output but also the input into academia.

Somewhat more difficult to deal with are those complaints that relate to physician availability. Often what is really intended by the complaint is an attempt to inform us that a return to the "good old days of house calls" would be more in keeping with what would satisfy their personal needs. Even on this touchy issue, however, people are beginning to understand that changing technology has made the house call anachronistic. Physicians are far more productive, efficient and, yes, available to more people in their offices and hospitals than they are traveling to patients' homes. Nevertheless, necessary house calls are still being made and a great deal of time and effort has gone into the development of comprehensive programs of continuing patient home care, the public can and does understand this if it is explained rationally.

What is most difficult to deal with, however, are the more emotionally laden problems between doctor and patient. What we hear is, "My doctor is so busy that he doesn't listen to me" or "I really can not understand what my doctor is saying." These are criticisms that indict us as human beings.

They are most often genuinely and sincerely leveled at our profession in good faith by a public that still holds us in high esteem. They merit our fullest consideration as a measure of our knowledge of the art of medicine rather than its science.

If those of us who are primary care physicians are to fulfill our role properly we must by word and deed convey our warm and sincere concern for those to whom we minister care. It is part of the very definition of the term primary care. Those of us who practice in specialties where there is less continuity of patient contact sometimes forget the emotional impact a serious illness can have on patient and family alike and we tend to concentrate on the illness rather than on the patient who is ill. We must recognize and allay the confusion and fear that accompanies these isolated episodes.

Let's never forget that patients are more than sources of income. They provide emotional support and gratification for each of us. In the long run they are also our greatest friends and allies and the majority of them will testify to the quality and integrity of our profession.

It only takes a few moments to say a kind word or to make a personal inquiry. It's always appreciated and in turn yields immeasurable satisfaction to each of us.

It takes effort to maintain that special combination of art and science that makes our profession so unique, but it is an effort well worth making.

Edward A. Kamens, M.D.,
*President*

# Reflections from the Dean's Office

## Weather Patterns

ROBERT U. MASSEY, M.D.

In an informal discussion among clinicians and basic scientists, someone asked if there were a new breed of internist. I recalled an earlier conversation in which a professor at another medical school said that the generation of academic physicians who had come of age during the two decades following World War II had been a different breed (he referred to that period as a "blip"), and that we are now returning to normal. An eminent biomedical scientist said that medicine had taken a wrong turn during those decades, and that we should have to pay for that mistake.

I would not quote anyone on this issue, not even myself, because observations like these are intended to provoke good conversation and may not be entirely serious, but they do suggest that change is in the air.

We have known that for some time. We sense changing political and social climate long before the weather front is upon us. No one would deny that there is a conservative mood in the western world; it may represent only a short rest in the midst of a period of exhaustingly rapid change, or it may be the beginning of a long quiet after a century of war, revolution, and technological excesses. We should need a special kind of satellite to see the social climate as clearly as we now can watch the terrestrial weather.

These times are of concern to the medical educator. The cries demanding change are in swaying balance with the voices insisting that we hold fast at any cost. Decision is perilous, there are never enough data, and in a time of change it seems as though all our values get caught up in the storm.

I believe it only seems that way, and unless we are thoroughgoing relativists, we must believe that some values, the important ones, remain in place even at the end of a civilization. And as for facts, once a thing has been proved, it stays proved. Most change, especially social change, may be quite superficial, except for those long historical sweeps that are too slow to perceive in a single lifetime.

"I buy an American journal, anything, *Harper's* magazine, the first article I happen to notice: "The Crisis of Medical Service." At once I find myself in the midst of the problem. Medicine has become too expensive, has become a commodity that can no longer be afforded. A new system of medical service must be found."

Henry Sigerist[1] wrote that in his diary almost 50 years ago. Eight years later he wrote, "Today the President read a message to Congress recommending the National Health Program which includes compulsory health insurance."[2]

During the decades following World War II, medicine, and society, invested heavily in biomedical research. In the late sixties prominent physicians were announcing their discovery that medicine was a social science (which Virchow had observed over a hundred years earlier). Later medicine was recognized as one of the humanities, and now its status as a clinical science (or art) has been rediscovered.

That recurring cycle is to be expected. Medicine is too vast and too deep to be seen whole and all at one time. Whichever of its aspects is ascendant will depend upon what we are prepared to see in the light of current social or political fashions. Try as we will we cannot pull away from those forces, and deny that we are being vouchsafed a new revelation.

Each new insight seems far better, more honest and true, than yesterday's insight, and clearly an improvement over what had been believed a decade ago. This is some kind of a law and the basis for fashion. Consequently when our rhetoricians discover clinical medicine, they appear to be denouncing science and technology; and when they rediscover science, for effect they must scoff, slightly, at clinical judgment. The clinician Sydenham and the scientist Harvey shared the same century but barely acknowledged one another.

The subject of all of our endeavors remains the same, however, and because that subject is a living organism, a member of the human family, and a person, medicine remains both an art and a science, beginning and ending in philosophy. The breed of physicians remains essentially the same, but varieties are brought forth by the changing social weather.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

# Commission on Hospitals and Health Care: Five Years of Litigation

JOHN Q. TILSON, ESQ.

The Connecticut Commission on Hospitals and Health Care became operative on October 1, 1973 under the provisions of Public Act 73-117. The ensuing five years have given rise to a substantial amount of litigation involving hospitals, nursing homes and the medical profession with results almost uniformly adverse to the Commission. The first case involving CHHC to reach the Connecticut Supreme Court was decided as recently as April 24, 1979.[1] Salmon Brook filed an appeal from a CHHC decision denying most of a proposed rate increase because the projected salaries for the owner-administrator ($33,000) and the nursing director ($30,906) were deemed to be excessive under "guidelines" used by the Commission. The court held that the so-called guidelines were obviously regulations which had not been adopted as required by the Uniform Administrative Procedure Act and hence were invalid.

CHHC's use of guidelines as regulations has been a constant theme in court decisions overruling Commission actions. Litigation started almost immediately after CHHC was established, with half of the hospitals appealing from the original rate decisions in the Fall of 1973.

One of the appealing hospitals asked for a court ruling permitting it to put the full rate into effect pending litigation and was turned down on a preliminary motion.[2] This incident is noteworthy in only one respect. With a single recent exception it constitutes the only occasion either by way of preliminary motion or final decision on which the Commission has won in any court.

All of the 1973 cases were ultimately settled to the satisfaction of the hospitals. In 1974 and 1975 the hospital budget review process was comparatively uneventful and no hospital appealed in either of these years.

In the Spring of 1976 the Commission turned to an out of state source for a new executive director who came to Connecticut with a conviction that much more drastic action was needed. The Summer of 1976 thus marked a real watershed in the activities of the Commission. In 1976 the budget cut ordered by CHHC was $44,000,000 or approximately six per cent of the total hospital budgets. This resulted in appeals by 31 of the 35 hospitals, culminating in a landmark decision by former Justice Alcorn in a case involving New Britain General Hospital.[3] The court restored the full budget for which the hospital had applied and concluded:

> "In summary, the actual procedure followed by the Commission was unconstitutional, illegal and arbitrary. Commencing with the arbitrary purpose to limit all hospital budgets to an eight per cent increase, its staff arrived, using the 'criteria' adopted, at budgets which in turn met the approval of the ad hoc committee and the Commission as described. Panel and Commission hearings on the plaintiff's appeal from the Commission's decision were held without reasonable notice and were not fair hearings."

The impact of the New Britain decision resulted in settlement of the remaining 30 appeals with overall cuts of approximately one and one-half per cent. The decision carried over to the 1977 budget review process. Thirty-four of the thirty-five hospitals were able to work out approved budgets for that year by negotiation. Danbury Hospital, the sole hospital to appeal, alleged that it had opened a new hospital with Commission approval and that the Commission had not given it enough money to operate the new institution. The court once again sustained the hospital in full.[4]

Last summer once again thirty-four of the thirty-five hospitals were able to reach an agreement with the Commission with respect to their budgets, involving cuts of approximately one per cent. The sole appeal (by Norwalk Hospital, again involving a new hospital) was eventually settled on the basis of restoration of most of the cuts.

More next month. . . . !

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JOHN Q. TILSON, ESQ., Legal Counsel to the Connecticut Hospital Association; partner in the firm of Wiggin & Dana, New Haven.

*This article was prepared at the request of the Connecticut Hospital Association.*

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Complete literature available on request from Professional Services Dept. PML.

# The Tragic Case of Karen Ann Quinlan

JOSEPH M. HEALEY, J.D.

April 15, 1979, marked the fourth anniversary of the entrance of Karen Ann Quinlan into coma. She apparently had ceased breathing for at least two fifteen minute periods. She had been resuscitated by her friends and by the police. The exact amount of time she spent without spontaneous respiration was not known. When she was brought to the emergency room, she was found to be experiencing respiratory distress secondary to an insult to her central nervous system of unknown origin. She was placed upon a respirator to manage that distress while the search for the nature of the insult to her central nervous system was carried out. In this simple manner, began a case which attracted world-wide attention, generated almost 900 pages of court documents and which remains today a symbol of our societal frustration in dealing with the complicated problems of medical technology, care for the dying person and criteria for determining that death has occurred.[1]

The widespread attention attracted by the Quinlan case was a mixed blessing. Although it encouraged public discussion of important issues, it resulted in the generation of unfortunate misunderstandings about the facts of the case and several of its key elements.[2] The constraints of time and space impose a need for condensing complex issues to meet acceptable editorial limits. Nonetheless, in at least three areas—the absence of medical certainty, the influence of the fear of malpractice upon Karen Ann Quinlan's physicians and the significance of a legislatively enacted statute recognizing criteria for determining that brain death has occurred—the damage done was significant and should have been avoided.

The original trial in this case was held in the Superior Court. Judge Muir rejected the petition of Joseph Quinlan to be appointed guardian of the person of his daughter, to allow the discontinuation of her respirator, and to restrain any party from carrying out the discontinuation. Though the Judge candidly expressed his compassion for Mr. Quinlan, he was unable to find any grounds on which the relief could be granted. He did appoint Mr. Quinlan guardian of the property of Ms. Quinlan, but he denied Mr. Quinlan the power to make any decisions related to her health care.

The Supreme Court of New Jersey heard an appeal of the case and reversed the holding of Judge Muir. In essence, the Court held that a patient's right of privacy should not be unenforceable because the patient is not legally competent to exercise it. The Court argued that a guardian should have the power to assert such a right on behalf of the patient. Chief Justice Hughes, writing for the Court, pointed out that physicians traditionally distinguish between curing the ill and easing the dying process. He wanted to find a way to free physicians from possible contamination of their judgment by self-protective concerns. He seized upon the idea of an "ethics" committee who would have the responsibility of determining whether there was any reasonable possibility of her emerging from her present state and returning to a cognitive state. This committee was authorized to review the decision of guardian and physician to discontinue treatment. If it found that there was no reasonable possibility of her regaining such a cognitive state, then they were to approve the decision, and the decision was to be implemented. The involvement of committee review was given great legal significance by the Court. Any participant in a decision made in compliance with this framework would be immune from any civil or criminal liability for the decision.

The committee mechanism envisioned by Hughes is not really concerned with "ethics" but rather with prognosis. Later formulations of the responsibilities of this committee have recognized this and have made appropriate changes in its title. The key fact remains that under the Quinlan decision, if such a mechanism is used, it is unnecessary to seek the support or approval of a court before proceeding.

Discussion of the policy implications of the Quinlan case and the attempts by states to come to grips with the problems it presents deserves special attention and will be continued next month.

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JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington.

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# EDITORIALS

## Hospice: Compassionate Terminal Care

Care of the dying patient has too long been a neglected area in the practice of medicine. Physicians, nurses and other health professionals have found the terminally ill patient to be an often overwhelming challenge. Formalized institutions such as the acute care hospital have been unable to fit such patients into the mainstream of their activities. Elsewhere in this issue of *Connecticut Medicine* is an exposition detailing the origin and present status of the hospice movement in Great Britain and, closer to home, in Connecticut. This enlightened program has provided a theory and practice of management of the terminal patient which gives the patient and his family care in a kind and compassionate environment providing physical and psychological support in a fashion not known as recently as twenty years ago.

A group of care givers in New Haven a decade ago recognized the unique aspects of hospice and using a combination of hard work and professional skills spiced with some good luck fashioned a home care program which has been administering to patient/families in the home since 1974. The next step in the local hospice effort which will offer care to patients in the entire State of Connecticut will open in the autumn of 1979 in the form of an in-patient facility in Branford housing forty-four patients and will be dedicated to the best precepts of medical care of patients with limited longevity.

This first building in the United States constructed to serve specifically as a hospice could not have become a reality without the efforts of a dedicated group of individuals and particularly Representative Robert N. Giaimo of the Third Congressional District and Governor Ella Grasso whose support resulted in both Federal and State appropriations for bricks and mortar. The Branford facility will offer not only care to the citizens of Connecticut but will also serve as a demonstration to other communities in America to emulate by establishing their own facilities.

An outgrowth of this aspect of The Connecticut Hospice was the recent organization of the Hospice Institute for Education, Training and Research, a non-profit foundation whose mission will be the training of personnel in the concept of hospice care. It is anticipated that the Institute will attract individuals from all parts of the United States to its symposia and training programs. These professionals will ultimately return to their own cities and towns and act as the catalyst for the founding of new hospices.

Cicely Saunders who conceived the first hospice to care for the terminal patient can be proud of the international stature that her idea has achieved in 1979. Hospice embodies all that each of us as physicians are dedicated to give our patients and their families. It is a successful effort to make the process of dying acceptable to psyche and soma.

Ira S. Goldenberg, M.D.

*Dr. Goldenberg is Professor of Surgery at the Yale University School of Medicine and was a founder of The Connecticut Hospice. He currently serves as Vice-President of the Board of Directors of The Connecticut Hospice and is President of the Hospice Institute for Education, Training and Research.*

## Psychiatry, Ethics and Politics

Billy Carter deserves better, so do we.

There's a peculiar tradition, nowhere stronger than in Washington, of attributing the embarrassing, inexplicable or illegal behavior of politically prominent figures to some kind of mental infirmity, preferably of a mild, temporary type. It serves to explain everything, and it lets us all breathe a sigh of relief: after all, the man himself wasn't ignorant, silly or wrong, he was just out of control. What he did was really done by some illness, by something with a name that doctors know, and not by the man himself. When he gets over it, as he surely will with the help of medical science, he'll be out of danger and so will we.

In recent weeks, for example, Billy Carter embarrassed the president with his deprecating demographic and anatomic references to Jews. Finally, after mounting pressures on both brothers, pressures for condemnation from Washington and for contrition from Plains, a solution emerged—naturally, simultaneously and independently—in both places. Billy was ill; and the illness wasn't just physical.

In Washington, one presidential adviser confided that "if Billy was well he wouldn't say that sort of thing." Another suggested, more specifically, that Billy's emotional health had deteriorated, mentioned alcoholism, and offered that his health problems may be so severe as to require professional attention. At a news conference, the president, in response to a question about Billy's remarks, refused to condemn him, explaining that Billy was "seriously ill."

And, in Plains, Billy decided to enter a hospital, his personal friend and physician speaking of bronchitis but, at greater length, of Billy's emotional symptoms: the anxiety, the shaking, the feeling of being "really uptight." Billy, the physician observed, had been under great stress for some time; in fact, as long as 10 months ago he had been hospitalized for exhaustion. The doctor denied the rumors of Billy's alcoholism, but other friends pointed to his chain-smoking and his chain-drinking, and attributed his condition to his personal, financial and public travails. Summarizing it all, one close friend commented, "He's been through an awful lot. The boy's tired."

All this, presumably, as a way of explaining those embarrassing remarks. Billy Carter wasn't himself. Those weren't his real ideas—or his real feelings. Under better circumstances, his views, as well as his expression of them, would be different. Now, under the influence of terrific pressures and possibly alcohol, his mind was different, and so, therefore, were his words. In effect, Billy had received—and, through his friends, had given himself—a diagnosis of mental illness. It was at once illuminating and reassuring. It brushed away ethical concerns and substituted for them medical ones. It provided explanation, and explanation became exculpation. It was diagnosis at its salvational best, an illustration of its rich potential for non-medical use.

The trouble is that with its use comes its abuse. As much as a diagnosis can save, it can also harm. Pressed into duty outside the medical realm, it corrupts us. We begin to make judgments about words and deeds as if they are only signs and symptoms. We divest ourselves—and others—of the responsibility for an ethical or legal accounting, and accept for ourselves—and others—only the need for a medical explanation. Sometimes that explanation is, in fact, valid; sometimes it does, justifiably, exculpate. But our attraction to such explanation is so great, our need for it so substantial, and our rush to it so common, that, too often, in the public sphere as well as in the legal one, we embrace it and are assuaged by it even when there is no justification at all for its use.

And just as diagnosis, so misused, corrupts us, it also corrupts itself. For the same reasons that it so powerfully saves, diagnosis can also powerfully condemn. Informally diagnosed this time, Billy Carter has less need to account for his words; but if we accept the diagnosis, whatever it is, then his next words, even if he wants them heard, will have less meaning. He will have been discredited, and with him everything he says. In fact, the beauty of psychiatric diagnosis as a tool for harm is so stark, and so attractive, that it is its major vulnerability. Not only does it invite use for discreditation; it has equal potential for far worse—for dehumanization, for intimidation, and for punishment. And, because it has such potential, it has been so used, or attempts have been made to so use it, in the political sphere; and not only in the political sphere, as we've heard in the Soviet Union, but also in the ordinary spheres of everyday life—in business, in industry, in the professions, in the military, and in our schools.

Billy Carter deserves better because he and his words deserve ethical and political judgment. If circumstances or illness have really compromised his mental capacities, then those who attribute his words to such a condition should realize that they are letting him off the hook at a price—they are undermining, possibly forever, the seriousness with which he can be taken. And, too, they should realize that they are asking us to overlook the meanings and implications of the words themselves.

And *we* deserve better. We need to protect our ability to judge social, legal and political issues in social, legal and political terms; there is a place for medical accounting, for a softening of personal responsibility, for extenuating explanations and exculpating conditions, but it is a place that should be carefully set aside and grudgingly granted. And, too, we need to protect the enterprise of legitimate psychiatric diagnosis itself; we need to be aware that, in the medical arena, it is usually a valuable process that can be the beginning of understanding and that can point the way toward treatment, while, in the public arena, it is a dangerous tool that can become the end of judgment and that can point the way toward its own corruption and abuse.

Walter Reich, M.D.

*Dr. Reich is a Washington psychiatrist and lecturer in psychiatry, Yale University School of Medicine.*

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# Letters to the Editor

**Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.**

## RADIAL ARTERY CANNULATION

*To the Editor:* Percutaneous radial artery cannulation is widely practiced and is a useful technique for the measurement of direct arterial pressure and for blood-sampling. I am describing a technique which is easy to perform and is effective.

After adequacy of circulation is established by Allen's test or other methods, the wrist is dorsiflexed and immobilized. Skin over the artery is infiltrated with a local anesthetic and a small skin cut is made using the tip of an 18 or 20 needle. Using palpation of the artery as a guide, the Catheter Placement Unit (Jelco Cathlon IV 18 or 20) is introduced through the skin opening at an angle of 20 to 30 degrees to the skin. Entrance into the artery is indicated by the pulsatile flow of blood. Posterior wall of the artery is also pierced until the bloodflow ceases. Now the needle is removed and an intravenous extension tubing is connected to the cannula with the tubing clamped at a distance of about 10 cms. from the tip. (Abbott Extension Set No. 4610 has a built-in clamp.) The cannula is slowly withdrawn. When the tip of the cannula comes back into the arterial lumen, arterial blood under pressure pushes the column of air in the intravenous tubing. Arterial pulsations are indicated by the movement of blood in the tubing. Cannula is then introduced during the systolic period when the arterial wall is dilated. The cannula is then pushed into the vessel and secured in place.

This technique has advantages over the commonly used technique of leaving the cannula open while withdrawing after insertion through the artery. Blood is lost when the arterial lumen is entered, and the arterial wall does not remain open for the insertion of the cannula.

The technique described above is easy to perform, safe, and does not need the use of complicated equipment.

J.A. Moses, M.D.

30 Kalan Circle
Fairfield, CT

1. Oh, TE and Davis, NJ: Radial artery cannulation. Anesthesia and Intensive Care 3: 12-18. 1975.

# Medical and Health News

Congress has approved a rescission of $83.3 million in health appropriations for FY 1979. The largest item cut from the budget was $37 million for construction of a new National Institute of Child Health and Human Development research building, followed by $24 million in capitation grants to schools of medicine, osteopathy and dentistry. It's been reported that some senators were angered by what they considered to be exaggerations by medical schools of the inflationary effect a funding cut would have on tuition levels. The House had originally voted to rescind only $61.8 million in the health field, but conferees agreed to the more stringent Senate position with little debate. While the $83.3 million figure is less than half of the $205 million that President Carter asked in health cuts, congressional staffers reportedly view the rescissions as an indicator of lean times to come for health programs.

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Renewal health planning legislation has started through the Congress. The Senate Human Resources Health Subcommittee made a few revisions in its bill (S 544), trimming the overall authorization level to just under $1 billion (down from $1.5 billion) and allowing planning agencies to write health systems plans on a biennial basis rather than annually. The House Commerce Health Subcommittee is examining two such bills: HR 3041, which is sponsored by Subcommittee Chairman Henry Waxman (D-Calif.), and the Administration's bill (HR 3167). Many provisions which drew opposition in last year's proposed legislation have been revised to avoid controversy. The extension of Certificate of Need (CON) to physicians' offices, for instance, is much more limited than in the past. Congress is expected to move quickly on a three-year extension of the planning act.

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A new effort has been launched to find alternative methods of reimbursing Health Maintenance Organizations (HMOs) for care provided to Medicare and Medicaid recipients. HEW's Health Care Financing Administration (HCFA) has awarded seven contracts totaling $1.4 million for demonstration projects in these areas. Less than 2 percent of Medicare and Medicaid patients are currently enrolled in HMOs. A spokesman for HEW blamed the low enrollment on lack of incentives under the law for such individuals to enroll in HMOs. Current provisions for reimbursement also appear to be at fault, since they do not sufficiently motivate HMOs to enroll higher-risk Medicare and Medicaid patients. HCFA is hoping that demonstration projects will pinpoint effective marketing and enrollment strategies for use in the future.—*AAFP Reporter*, May 1979.

# 1979 CSMS Annual Meeting

CONNECTICUT STATE
MEDICAL
SOCIETY

### CHANGING OF THE GAVEL

Jerome K. Freedman, M.D., of New Haven, left, retiring President of the Connecticut State Medical Society, presents the President's gavel, mounted on a plaque, to the 142nd President of the CSMS, Dr. Edward A. Kamens, of Fairfield.

The ceremony took place during the recent Annual Meeting dinner of the Society held at the Hartford Hilton Hotel.

The Presidency of the State Medical Society began back in 1792 with the election of Leverett Hubbard, M.D., of New Haven, as the first president of this, the third oldest medical society in the country.

CONNECTICUT STATE
MEDI
SOC

### PAST PRESIDENT'S AWARD

Dr. Jerome K. Freedman, left, receives the Past President's award, a silver Revere bowl with the seal of the State Medical Society embossed upon it and the President's pin.

Presenting the award is Dr. Andrew Canzonetti of Waterbury, Chairman of the Council of the Connecticut State Medical Society.

CONNECTICUT STATE

### AMA-ERF FUNDS AWARDED

Dr. Robert U. Massey, left, Dean of the University of Connecticut Medical School and Dr. Lawrence K. Pickett, Associate Dean of Clinical Affairs, Yale University Medical School, receive checks from Mrs. Thomas Masterson, outgoing president of the CSMS Auxiliary and from Dr. Freedman.

The checks totalling $6,531.72 are the result of fund raising activities of the Auxiliary here in Connecticut on behalf of the American Medical Association's Education and Research Foundation.

# FROM THE EXECUTIVE DIRECTOR'S OFFICE

160 St. Ronan Street, New Haven, Conn. 06511
Telephone 865-0587

Francis G. Sweeney
*Assistant Executive Director*
*Public Affairs*

Timothy B. Norbeck
*Executive Director*

Josephine P. Lindquist
*Associate Executive Director*

Robert J. Brunell
*Assistant Executive Director*
*Scientific Activities*

## SUMMARY OF PROCEEDINGS
## HOUSE OF DELEGATES—ANNUAL MEETING
## Hartford, Connecticut—May 2, 1979

### Reports and Addresses

The House received reports, addresses and/or remarks from the President, the Secretary, the Treasurer, the Council, Delegates to AMA, the Executive Director, the Standing Committees, Representatives and Advisors, the President of the Auxiliary to CSMS, and the delegates from the medical societies in New York, Vermont, New Jersey and Massachusetts.

At the Annual Dinner of the Society, the incoming President, Edward A. Kamens, Fairfield, made his inaugural address which was published in the May issue of Connecticut Medicine.

### Election of Officers and Others

With minor amendments, the House voted to approve the published report of the Nominating Committee (the Council). Officers elected were:

President: Edward A. Kamens, Fairfield
President Elect: W. Raymond James, Essex
Vice-President: Andrew J. Canzonetti, Waterbury
Secretary: Louis C. Backhus, Waterbury
Treasurer: John J. Mendillo, New Haven
Speaker of the House of Delegates:
  Stuart Ragland, Jr., Colebrook
Vice-Speaker of the House of Delegates:
  Joseph S. Sadowski, Hartford
AMA Delegate: Orvan W. Hess, North Haven
Alternate AMA Delegate:
  Isadore H. Friedberg, Newington
Councilor-at-Large:
  Jerome K. Freedman, New Haven

### Presentations and Awards

**Presentation to Retiring President:** In recognition of his efforts as President of the Society during 1978-79, Jerome K. Freedman, New Haven, received an engraved silver bowl and past President's pin. The presentations were made by Andrew J. Canzonetti, Waterbury, Chairman of the Council.

**Presentation to Incoming President:** A plaque with a gavel, symbolic of the office of President of the Society, was presented to Edward A. Kamens, Fairfield, by the retiring President, Jerome K. Freedman, New Haven.

**AMA-ERF Grants to Medical Schools:** Provided by the AMA Education and Research Foundation, unrestricted grants were awarded as follows: To the Yale University School of Medicine—$5136.72. Accepting for Yale was Lawrence K. Pickett, Associate Dean for Clinical Affairs; to the UConn School of Medicine—$1395.00. Accepting for UConn was Robert U. Massey, Dean.

### Summary of Actions Taken

All items of business not calling for specific action by the House were accepted directly for filing. Items calling for action to be taken by the House were heard by Reference Committees and based on the reports of the Reference Committee, were acted on as follows:

**1) Development of Disaster Plan: Voted to adopt a resolution, the resolved portion of which follows:**

RESOLVED: That the Council of the CSMS be directed to determine through its standing Committee on Emergency Medical Services the status of disaster plans in Connecticut for dealing with a nuclear accident.

**2) Title XIX Payment Schedule: Voted to adopt a resolution, the resolved portion of which follows:**

RESOLVED: That CSMS House of Delegates condemns any intentional miscoding of services rendered to Title XIX Patients. We decry any implication that such practice is widespread among its membership. We urge the Connecticut Department of Income Maintenance to examine its procedures of coding, and to rectify inadequacies, prior to implying that widespread wrongdoing exists, and be it further

RESOLVED: That the Connecticut State Medical Society House of Delegates mandates the Council of the Connecticut State Medical Society to continue and increase its efforts to achieve reasonable and timely reimbursement for physician care of Title XIX patients, and be it further

RESOLVED: That the Connecticut State Medical Society House of Delegates urges physicians to continue to care for Title XIX patients to the best of their ability, in the face of inadequate levels of reimbursement.

3) **Congressman Robert N. Giaimo: Voted to adopt a resolution, the resolved portion of which follows:**

RESOLVED: That this House direct the Council to frame an appropriate sentiment of congratulations to Congressman Robert N. Giaimo on the occasion of his becoming the Congressman with the longest term of continuous service in the history of the state.

4) **Federal Legislative Effort by the AMA: Voted to adopt a resolution, the resolved portion of which follows:**

RESOLVED: That the CSMS request immediate action by the AMA to achieve the passage of federal legislation for the following purposes: The permanent protection of the responsibility of our profession to create, modify and apply standards of ethics, conduct, education and competence for its members: And the assurance that these functions will remain free of any prior restraint or prior approval by the federal government, and that the CSMS urge the AMA to consider this a matter of the highest priority, to be pursued until completed.

5) **Rights of Professional Organizations: Voted to adopt a resolution, the resolved portion of which follows:**

RESOLVED: The Council of CSMS be directed to pursue the question of state legislation to protect the rights of professional organizations to establish standards of ethics, conduct, education and competence for their members.

6) **Federal Trade Commission Complaint: Voted to adopt a resolution, the resolved portion of which follows:**

RESOLVED: That the House of Delegates instruct the Council to carry the appeal as far as needed to either achieve a successful conclusion or exhaust all avenues of redress. This House should also advise the Council that at this juncture the cost of this activity seems less important than the activity itself.

7) **Miscellaneous Actions taken:**
   a) Hilliard Spitz, New London, was commended for his assiduous efforts during his term as Treasurer of the Connecticut State Medical Society.
   b) Appreciation was expressed to Charles M. Krinsky, New London, for his diligent work as Vice-Speaker of CSMS House of Delegates.

### Amendments to Bylaws RE: Administrative Procedure

The House of Delegates adopted five amendments to the Bylaws (Article IV—Membership, Section 4—Life Members, Paragraph 1 and Section 5 - Student Members, Paragraph 1, Article VII—The Council, Section 5 - Meetings, Paragraph 2 Quorum and Section 6 - Power to Fill Vacancies, and Article XI—Standing Committees, Section 1 - Purpose and Elections, Paragraph 6 - Vacancies and Interim Appointments); the purposes of which are to simplify Council meeting procedures and to facilitate the transaction of its business. The first and second amendments allow for Life and Student Members to be approved by the Executive Director of the Society who will subsequently report his action to the Council. The third amendment reduces the size of the quorum for Council meetings to one-third plus one of the voting members, with representation from at least five counties. The fourth amendment authorizes the President to fill a vacancy or make an interim appointment on any standing committees or in the posts of representatives and advisors, until an action by the House of Delegates at the next Annual Meeting. The fifth amendment authorizes the Council to fill a vacancy which may occur in any elective office, board, or committee until the next Annual Meeting of the House of Delegates.

## In Memoriam

**BEAUCHAMP, LAWRENCE A.,** University of Vermont, 1944. Dr. Beauchamp was a general practitioner in the New Haven area since 1944. Dr. Beauchamp served as a U.S. Army officer during World War II in the European Theater. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Beauchamp died April 17, 1979, at the age of 60.

**DELLIGAN, FRANCIS W.,** Georgetown Medical School, 1941. Dr. Delligan was a radiologist in the Hartford area since 1942. In 1945, he became the first full-time director of radiology at St. Francis Hospital. After several years in private practice, he returned to the hospital and retired in 1974. Dr. Delligan was a member of the Hartford County Medical Association and the Connecticut State Medical Society. He died April 10, 1979, at the age of 63.

**FROST, LAWRENCE H.,** University of Vermont, 1913. Dr. Frost was a general practitioner in the Hartford area from 1913 until his retirement in 1968. He served in the Army Medical Corps during World War I, and was Plainville's Medical Examiner from 1930 to 1960. Dr. Frost died April 18, 1979, at the age of 90. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society.

# NEW MEMBERS

## FAIRFIELD COUNTY

**William E. Berger, M.D.**, Bridgeport
**David H. Bushell, M.D.**, Bridgeport
**Harold S.R. Byrdy, M.D.**, New Canaan
**Arnold E. DoRosario, M.D.**, Bridgeport
**Donald W. Edwardson, M.D.**, New Canaan
**Raymond M. Gabriele, M.D.**, Bridgeport
**Geoffrey S. Gladstein, M.D.**, Fairfield
**Paul B. Goldberg, M.D.**, Bridgeport
**Enrique Hidrobo, M.D.**, Bridgeport
**Oscar H. Lascano, M.D.**, New Fairfield
**Richard N. Lopatin, M.D.**, Fairfield
**Bruce M. McDonald, M.D.**, Fairfield
**Kesavan G. Nair, M.D.**, Norwalk
**Michael J. Newton, M.D.**, Stamford
**Dan C. Omohundro, M.D.**, Fairfield
**Fern L. Perlman, M.D.**, Westport
**Charles H. Rousell, M.D.**, Greenwich
**Diane H. Schetky, M.D.**, Wilton
**Mukesh H. Shah, M.D.**, Bridgeport
**Vibhavary M. Shah, M.D.**, Fairfield
**Betty Ann Ward, M.D.**, Bridgeport
**Myra Waynik, M.D.**, Bridgeport
**Jesse S. Wexler, M.D.**, Westport
**Evangelos D. Xistris, M.D.**, Stamford

## NEW LONDON COUNTY

**Charles W. Andrias, M.D.**, New London
**Louis V. Buckley, M.D.**, New London
**Steven M. Curland, M.D.**, Norwich
**Miecrylou M. Deren, M.D.**, New London
**Sanford A. Greenhouse, M.D.**, Gales Ferry
**James Kelly, M.D.**, New London
**Robert A. Linden, M.D.**, Niantic
**David D. Thompson, Jr., M.D.**, Niantic
**Joseph P. Zeppieri, M.D.**, New London

## NEW HAVEN COUNTY

**Boris M. Astrachan, M.D.**, New Haven
**Thelma V. Batiancila, M.D.**, Milford
**John L. Cornog, Jr., M.D.**, New Haven
**Charles B. Cuono, M.D.**, New Haven
**Ronald J. D'Andrea, M.D.**, Waterbury
**Paul R. Feldman, M.D.**, New Haven
**James R. Flink, M.D.**, New Haven
**Bernard S. Jay, M.D.**, Madison
**Charles J. Kopriva, M.D.**, New Haven
**Richard E. Kremer, M.D.**, North Haven
**Terry R. Light, M.D.**, New Haven
**Stephen J. Moses, M.D.**, Derby
**Novello E. Ruggiero, M.D.**, Waterbury
**Arthur G. Spector, M.D.**, New Haven
**Adam Wesolow, M.D.**, New Haven
**Peter D. Williamson, M.D.**, West Haven

## HARTFORD COUNTY

**Karoline Ascher, M.D.**, Rocky Hill
**David L. Brown, M.D.**, Bloomfield
**Alan D. Drezner, M.D.**, Hartford
**Edward M. Ewald, M.D.**, East Granby
**Paul L. Filippini, M.D.**, Somers
**Robert M. Frost, M.D.**, West Hartford
**Allen D. Kallor, M.D.**, New Britain
**John C. Madigan, Jr., M.D.**, Hartford
**Gerald V. McAuliffe, Jr., M.D.**, New Britain
**Richard B. Meyer, M.D.**, Hartford
**N.A.C. Mohanraj, M.D.**, Newington
**Stephanie H. Mullany, M.D.**, Hartford
**Alejandro Murcia, M.D.**, Manchester
**Illsuk Oh, M.D.**, Manchester
**Jayantkumar C. Patel, M.D.**, Hartford
**John M. Puskas, M.D.**, Glastonbury
**James S. Rosokoff, M.D.**, Hartford
**Victor S. Roth, M.D.**, Manchester
**Robert A. Rothenberg, M.D.**, Avon
**Behzad Satvat, M.D.**, Hartford
**Ferdinand Sauer, M.D.**, New Britain
**Richard H. Simon, M.D.**, Farmington
**Thomas J. Spackman, M.D.**, Farmington
**Edwin A. Spath, M.D.**, Hartford
**Barry S. Steckler, M.D.**, New Britain
**Stuart R. Sugarman, M.D.**, Farmington
**Evelyn S. Tan, M.D.**, Manchester
**Bennett S. Walstatter, M.D.**, West Hartford
**Donald S. Weinberg, M.D.**, New Britain
**Annemarie S. Welch, M.D.**, Woodbridge
**Joseph T. Witek, M.D.**, Hartford

## LITCHFIELD COUNTY

**Martin D. O'Connor, M.D.**, New Milford
**Estella K. Pua, M.D.**, Torrington
**Sayedur Rahman, M.D.**, Terryville
**Prashant A. Rodrigues, M.D.**, New Milford
**Herbert H. Schettler, M.D.**, Torrington

## MIDDLESEX COUNTY

**Daniel Belin, M.D.**, West Hartford
**James C. Costin, M.D.**, Guilford
**Helen Davis, M.D.**, Middletown
**Kassem Khybery, M.D.**, Colchester
**Sandra B. Raff, M.D.**, Cromwell
**Alan M. Spagnola, M.D.**, Madison

## WINDHAM COUNTY

**Lawrence H. Bernstein, M.D.**, Storrs
**Kenneth R. Dardick, M.D.**, Storrs
**Anthony A. Ferrante, M.D.**, Willimantic
**Ronald W. Klare, M.D.**, East Woodstock
**Bruce T. Lyman, M.D.**, Woodstock
**Walter T. McPhee, M.D.**, Willimantic
**Yolanta E. Meya, M.D.**, Willimantic
**Edward S. Sawicki, M.D.**, Willimantic
**Roger Schmid, M.D.**, Putnam
**Charles A. Shooks, M.D.**, Willimantic

# PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

## OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

### EMERGENCY ROOM

Full time position available at modern 225-bed community hospital in eastern CT; 33,000 visits yearly; 42-hour work week; salary competitive. Send CV to G.L. Springer, M.D., Chief of Emergency Room Services, William W. Backus Hospital, 326 Washington St., Norwich, CT 06360.

### FAMILY PRACTICE

Family Practice Physician (will consider Pediatrician or Internist) for well established neighborhood clinic working 35 hours a week. Salary comparable to full time emergency room physicians in large size hospital. Fringe benefits. Contact Gert Wallach, M.D., M.P.H., Director of Health, Waterbury, CT (203) 574-7680.

### INTERNAL MEDICINE

Internist with subspecialty in Cardiology, Gastroenterology or Pulmonary to associate with established Internists in medium size community, southern New England, Hospital University affiliated. Close to shoreline, Hartford and New Haven. Abundant recreational opportunities. Send CV to CSMS to be forwarded.

### PSYCHIATRY

Part or full-time position for psychiatrist in specialized substance abuse facility. In-patient and out-patient services. Methadone Maintenance Program. Duties include service as Unit Chief, member of team of psychiatrists and physicians, evaluations and supervision of clinical staff. Contact: Administrator, Blue Hills Hospital, 51 Coventry St., Hartford, CT 06112 (203) 566-4405.

Psychiatrists and Physicians to work in specialized programs—drug dependence, alcoholism, geriatric rehabilitation, and general psychiatry. Setting is dynamic, decentralized and community oriented. Training affiliation with Yale. Opportunity for private practice or consultation. Elig. for CT licensure required. Salary commensurate with experience and training. Liberal benefits. Send all particulars in first letter including references to: Mehadin K. Arafeh, M.D., Supt., Connecticut Valley Hospital, Box 351, Middletown, CT 06457. EOE.

## PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

### ALLERGY

July '79. Age 32. FLEX. Am. Bds., cert.-ped. MD: India. Int., res. and fellowship: Long Island College Hosp. Wishes assoc. type practice in med. community. Contact CSMS-Allergy/YKR.

### ANESTHESIA

Oct. '79. Age 40. AB-elig. MD: Saigon Faculty of Med. Res.: Mary Hitchock Mem. Hosp., NH. Fellowship: Dartmouth. Solo, grp. or assoc. practice in med. or sm. community. Contact CSMS/Anes.-NVN.

Available now. Age 29. MD, int., and res.: Iraq. Wishes grp., assoc. or institutional practice in CT. Adnan Alduliami, M.D., 7 Williams Blvd., Lake Grove, NY 11755.

July '79. Age 29. AB-elig. MD: India. Int. and res.: Monmouth Med. Ctr. Also res.: Bronx Lebanon Med. Ctr., NY. Solo or grp. practice desired, in med. or small community. Raveendra Limaye, M.D., 335-D Third Ave., Long Branch, NJ 07740.

July '79. Age 30. AB-elig. MD: India. Int.: Muhlenberg Hosp., NJ. Res.: Albert Einstein, NY. Presently working at Einstein as attending anes. and instructor. Jitendra G. Patel, M.D., 133-52 Avery Ave., Flushing, NY 11355.

### DERMATOLOGY

June '80. Age 27. Conn. license. Nat'l. bds., elig. 6/80. MD: Univ. of Miami. Int.: Jackson Mem. Hosp. Res.: Baylor. Will consider all types of practice except industrial in CT. Sandy Martin, M.D., 2475 Underwood #369, Houston, TX 77030.

### INTERNAL MEDICINE

**Cardiology:** July '79. Age 32. AB-elig. MD: India. Int.: Homot Med. Ctr., PA. Res.: VA Hosp., NY. Fellowship: Beth Israel Med. Ctr., NY. Interested in invasive and non-invasive card. including nuclear card. Solo, assoc. or institutional practice desired in large or med. community. R.K. Bhalla, M.D., 353 East 17th St., #8F, NY, NY 10003.

Aug. '79. Age 27. Nat'l. bds., elig. MD: St. Univ. of NY-Downstate. Int. and res.: Brookdale Hosp., NY. Wishes solo, grp. or assoc. practice in large or med. community. Contact CSMS/IM-RC.

July '79. Age 29. Nat'l. bds., cert. MD: Georgetown. Int. and res.: Dartmouth. Also res.: Northport VA Hosp. Wishes grp. or assoc. practice. Admissions privileges to a Univ.-affil. teaching hosp. Marilyn Coruzzi, M.D., 70 Forest Dr., E. Northport, NY 11731.

**Gastroenterology:** July '80. Age 29. Conn. license pending. Nat'l. bds., cert. MD: Univ. of Michigan. Int. and res.: Thomas Jefferson Univ. Fellowship: UConn-GI. Grp. or assoc. practice in large community. Contact CSMS/IM/GAST.-IML.

**Pulmonary:** July '79. Age 32. FLEX. AB-elig. MD: Iran. Int. and res.: Danbury Hosp. Fellowship: Wayne State. Solo, grp. or assoc. practice in medium community and hosp. with at least 200 beds. Said F. Mahmoud, M.D., 20855 Lahser Rd., Apt. 606, Southfield, MI 48034.

**Hematology and Oncology:** July '79. Age 31. FLEX. AB-cert. MD: Ohio State. Int. and res.: Univ. of Oregon. Fellowship: Washington Univ., St. Louis. Wishes assoc. practice in large community. George M. Pipoly, M.D., 407 Cloisters Walk, Kirkwood, MO 63122.

Summer '79. Age 34. Nat'l. bds., elig. MD: Stanford. Int. and res.: UCLA. Wishes assoc. practice in either north/southwestern portions of CT. Wife also Internist. Michael L. Shorenstein, M.D., 1454 Yale St., #2, Santa Monica, CA 90404.

Summer '79. Age 32. Nat'l. bds., elig. MD: Stanford. Int. and res.: UCLA. Wishes grp. practice in either north/southwestern portion of CT. Husband also Internist. Rosalind G. Shorenstein, M.D., 1454 Yale St., #2, Santa Monica, CA 90404.

**Oncology:** Aug. '79. Age 33. Nat'l. bds., cert. MD and fellowship: Duke. Int.: Methodist Hosp., TX. Res.: Columbia-Presbyterian. Solo, grp., assoc. or institutional practice in large community. Interested in doing a large portion of IM as well as Onco. Carol D. Silver, M.D., 1619 Third Ave., Apt. 4G, NY, NY 10028.

May '79. Age 31. FLEX. AB-elig. Presently in practice. MD: Kyungpook Nat., Korea. Int. and res.: Mt. Sinai Hosp., Elmhurst, NY. Wishes solo, institutional or industrial practice. Contact CSMS/IM-BKY.

July '79. Age 32. Nat'l. bds., cert. MD: UConn. Int. and res.: Kaiser Hosp., CA. Grp. or HMO practice in CT. Experience working with nurse practitioners. Personal interest in Infectious Disease. William H. Yurgilevich, M.D., 722 20th Ave., San Francisco, CA 94121.

**Gastroenterology:** July '79. Age. 30. Nat'l. bds., elig. MD: Emory. Int. and res.: Charity Hosp.-Tulane. Fellowship: Westchester Med. Ctr., NY. Solo, grp. or assoc. practice in Southwestern CT within 1 hr. of commuting distance of NY. Bennett H. Bruckner, M.D., 192 Garth Rd., Apt. 6M, Scarsdale, NY 10583.

## NEUROLOGY

July '79. Age 30. FLEX. AB-elig. MD: Government Med. Coll., India. Int.: St. Francis Hosp., PA. Res.: Hosp. of Med. Coll. of PA. Will consider all types of practice. Hungi P. Eswara, M.D., #843 School Lane House, 5450 Wissahickon Ave., Philadelphia, PA 19144.

## OBSTETRICS AND GYNECOLOGY

Aug. '79. Age 30. Conn. license. Nat'l. bds., elig. MD: Jefferson Med. Coll., PA. Int. and res.: St. Francis Hosp., Hartford, CT. Wishes grp. practice in community of 25,000-100,000 pop. Contact CSMS/OB/GYN-DOT.

July '79. Age 43. Conn. license. AB-cert. Presently in practice. MD: Hadassah Med. Sch., Israel. Int.: Highland Park Gen. Hosp., Mich. Res.: Jewish Hosp. Med. Ctr., Brooklyn. Solo, grp., assoc. or academic practice desired in large or med. community. Contact CSMS/OB/GYN-MV.

## OPHTHALMOLOGY

July '80. Age 28. Nat'l. bds., Presently in practice. MD, Ph.D.: Duke. Int.: Presbyterian Hosp., CA. Res.: Univ. of CA. Assoc., solo or grp. practice in med. or large community. Carl Fromer, M.D., 145 Carmell St., Apt. 7, San Francisco, CA 94117.

## ORTHOPEDICS

**Or Internal Medicine:** July '79. Conn. license. Age 68. MD: NY Med. Coll. Wishes grp. practice in CT. Been in practice 40 years in NY. Silvio J. Jampaglia, M.D., 650 E. 49th St., Brooklyn, NY 11203.

Available immediately. Age 52. AB-elig. MD and int.: India. Res.: Metropolitan Hosp. and Mary Immaculate Hosp., both in NY. Fellowship in hand surg., Kings County, NY. Will consider grp., assoc. or instit. practice in large or med. community. Sheroo Kohli, M.D., 5021 Aurora Ave., Des Moines, IA 50310.

## PATHOLOGY

July '79. Age 31. Nat'l. bds., elig. MD and int.: India. Res.: Christ Hosp., Ill. and Med. Coll. of PA. Grp., assoc. or instit. practice desired in CT. Punita P. Kothari, M.D., 5990 Henry Ave., #4, Philadelphia, PA 19128.

## PEDIATRICS

Availability negotiable. Age 37. Nat'l. bds., elig. Presently in practice. MD: NY Med. Coll. Int. and res.: Albany Med. Will consider all types of practice in large or med. community in CT. Stephen B. Cook, M.D., Box 323, R.D. #1, Peterborough, NH 03458.

July '79. Age 29. AB-elig. MD: India. Int.: St. Vincent's Med. Ctr., NY. Res.: Miamonides Med. Ctr., NY. Subspecialty-endocrinology. Wishes grp., assoc. or instit. practice in CT. Seshagiri Rao, M.D., 950 49th St., Apt. #2G, Brooklyn, NY 11219.

Sept. '79. Age 31. Nat'l. bds., cert. Presently in practice. MD: Harvard. Int. and res.: Harbor Gen. Hosp., CA. Fellowship: National Institutes of Health, MD. Grp. or assoc. practice in med. community. Contact CSMS/Ped.-JAW.

July '79. Age 35. Conn. license. AB-elig. MD and int.: Trivandrum Med. Coll., India. Res.: NY Med. Coll. Wishes solo, grp. or institutional practice in CT. Roy C. Gomez, M.D., D-9, 300 Lookout Ave., Hackensack, NJ 07601.

July '79. Age 30. AB-elig. MD: Yonsei Univ., Korea. Int.: Detroit-Macomb Hosp. Res.'s.: Worcester City Hosp., Mass. and Lincoln Med. Ctr., Bronx, NY. Wishes grp., assoc., institutional or clinic position in CT. Boo Woong Lee, M.D., 1160 Midland Ave., #8M, Bronxville, NY 10708.

July '79. Age 30. AB-elig. MD: India. Int. and res.: Metropolitan Hosp. Ctr. and Westchester Cty. Med. Ctr. Wishes grp., institutional or HMO in med. community in CT. Valsamma Samuel, M.D., Westchester County Med. Ctr., Valhalla, NY 10595.

## PSYCHIATRY

July '79. Age 27. Nat'l. bds. Presently in practice. MD: Univ. of Puerto Rico. Int.: United Hosp., NJ. Res.: Sheppard and Enoch Pratt, MD. Fellowship: Boston Univ. Wishes grp. practice. Reinaldo De Los Heros, M.D., 100 Queen Anne's Dr., Weymouth, MD 02189.

## SURGERY

Oct. '79. Age 34. Nat'l. bds., cert. Presently in practice. MD: Jefferson. Int. and res.: Cooper Med. Ctr. Wishes grp. or assoc. practice in large or med. community. George W. Hager, III, M.D., R.D. #7, Box 7099, Stroudsburg, PA 18360.

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July '80. Age 31. AB-elig. '80. MD: Univ. of Guadalajara. Int.-surg.; res.-urol.: NJ Coll. of Med. and Dent. Wishes solo, grp. or assoc. practice in CT. Vincent J. Lanteri, M.D., 689 Passaic Ave., Clinton, NJ 07012.

Aug. '79. Age 32. Nat'l. bds., elig. MD: Tufts. Int., res. and fellowship: Univ. of Colorado Med. Ctr. Solo, grp. or assoc. practice in large or med. community in CT. Charles E. Roy, M.D., 1533 Oneida St., Denver, CO 80220.

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# Connecticut Medicine

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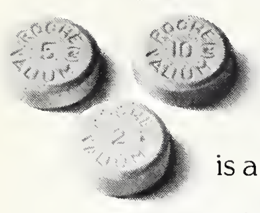

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# Selective Treatment of Burn Patients

## Two Year Experience of the Burn Service at Hartford Hospital

DONALD M. CLOUGH, M.D. AND PHILLIP E. TROWBRIDGE, M.D., F.A.C.S.

**ABSTRACT—Seventy-five patients required hospitalization at Hartford Hospital for significant burn injuries between January 1976 and January 1978. Eighty per cent of these patients had burn injuries of less than twenty per cent of the body surface area. Three deaths occurred in the entire group and all had burn injuries greater than thirty-five per cent BSA. Forty-one patients had partial thickness burns which did not require skin grafting. Seventeen patients with full thickness burns were selected for early excision and immediate skin grafting. The average hospital stay for this group of patients was nineteen days and there was minimal physical disability. Because of delay in transfer or underlying medical problems, seventeen patients with full thickness burns were treated with conventional debridement, topical antibacterial therapy and delayed grafting. The average hospital stay for this group was forty days and complications were more frequent in this group. Careful selection of treatment for patients with burn injuries results in optimal care.**

The recent two-year experience of the in-patient Burn Service at Hartford Hospital has been reviewed. This report describes the composition and modus operandi of our Burn Service, details our patient population and results of treatment and concludes with recommendations based upon this experience.

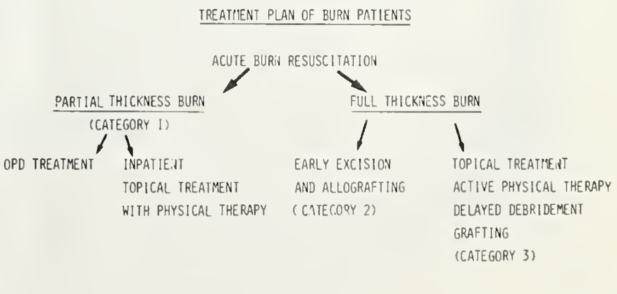
### The Burn Service

Six attending general and plastic surgeons plus assigned house staff physicians are responsible for the Burn Service. The burn team consists of burn nurses, physical and occupational therapists, a dietitian, social worker, psychiatrist and the above physicians. All patients admitted with burn injuries are assigned to this service and are initially cared for in the surgical intensive care unit when necessary until stable or are admitted directly to our designated burn nursing unit. This unit is staffed and equipped to optimize care of the burn patient. Standing nursing orders and protocols are utilized to initiate the patient's care. Fluid resuscitation with Lactated Ringers solution was standard during the period of this review.

### The Treatment Plan

During the first twenty-four hours post burn an attempt is made to separate the patient into one of three categories: (1) partial thickness burn only, no grafting anticipated; (2) full thickness or deep dermal burn and the patient will benefit from early excision and skin grafting; (3) full thickness or deep dermal burn but the patient is not a suitable candidate for the early excision technique. (Figure 1)

Figure 1



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DONALD M. CLOUGH, M.D., formerly, Chief Resident in Surgery, Hartford Hospital; presently, Lieutenant Commander, U.S. Navy Medical Corps, Chief of Surgery, U.S. Naval Hospital, Quantico, VA.

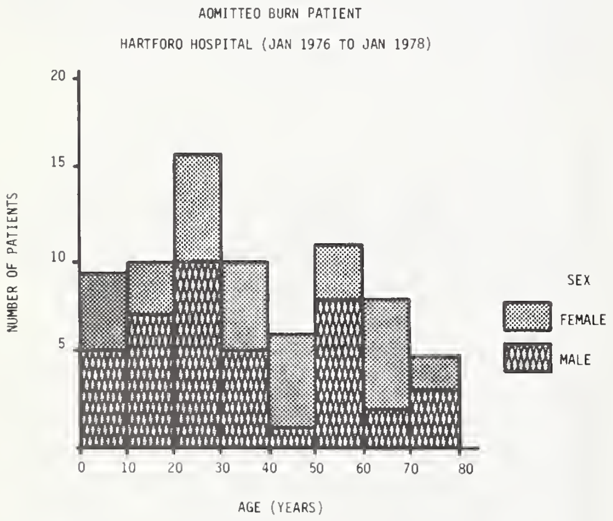
PHILLIP E. TROWBRIDGE, M.D., Senior Surgical Staff Hartford Hospital; Director, Burn Service Hartford Hospital; Clinical Associate in Surgery, University of Connecticut Health Center.

Patients are selected for the early excision and primary grafting technique if: (1) the total burn is less than forty per cent BSA; (2) deep dermal burn involves critical functional or cosmetic areas: hands, axilla, joints, neck, ears. Patients are felt not to be suitable candidates for early excision if they have sustained respiratory tract burn injury, are unstable medically, have a past history of recent myocardial infarction, progressive angina, marked chronic pulmonary disease, advanced liver disease, impending delirium tremens or other medical conditions thought to preclude major surgery and anesthesia within four days. Several patients were transferred to Hartford Hospital more than three days after sustaining their burn injury so were forced into this delayed treatment group.

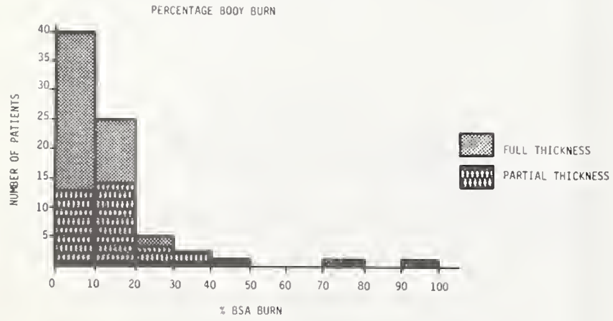
## Results

Seventy-five patients required hospitalization for significant burn injury. The age and sex distribution are shown in Graph 1. One-third of the patients were over age fifty years. Two of the three deaths occurred in patients in this older group. The percentage of body surface area burned is recorded in Graph 2. Eighty per cent of the patients had burns less than twenty per cent BSA. All of the deaths occurred in patients with burns greater than thirty-five per cent BSA.

Graph 1



Graph 2



Forty-one patients were treated in category one as partial thickness burns. Body surface area burn ranged from one to twenty per cent in this group. Local treatment of the burn wound consisted of thorough cleansing, shaving, debridement and dressing with a topical agent. Silver sulfadiazine cream was used in thirty patients. Topical Neomycin, Gentamycin sulfate, Iodophor foam, Furacin or simple nonadherent gauze with occlusive dressings were used according to physician preference in the remaining eleven patients. If the burn wound lent itself to dressings, they were used for patient comfort and to allow increased independence and mobility. Burns of the face and perineum were treated with an open technique using the agents mentioned.

Seventeen patients were selected for category two and early excision and grafting was performed. This was carried out within the first five days post burn on patients ranging in age from two to seventy-five years. (Table 1) The average age was thirty-nine years. Body surface area burn ranged from one to twenty-five per cent except in one fifty-five-year-old male who presented with an eighty-five per cent incineration burn. The length of hospital stay varied from two to fifty-one days, however the average stay was nineteen days. Minimal physical or psychologic disability has been the rule in these patients and only one patient required subsequent reconstructive surgery.

Seventeen patients were diagnosed as having full thickness burns, but were not suitable candidates for the early excision technique. These patients comprise the category three group (Table 2) and were treated with conventional topical therapy, repeated debridement and subsequent allografting. These patients ranged in age from seventeen to seventy-five years, the average age being forty-four years. Body surface area burn ranged from one to forty per cent, the average being fourteen per cent. The specific reasons for selection into this delayed grafting group are listed in Table 2. Delay in seeking medical care, delayed hospital transfer, burn wound infection and underlying medical or psychiatric problems were the principle reasons. The length of hospital stay varied between sixteen and eighty-one days with the average being forty days. Individual patient complications are also recorded in Table 2 and consisted of: sepsis, graft failure, temporary contractures requiring vigorous splinting and physical therapy, pneumonia and death in two patients.

## Discussion

It has been known for years that selected patients with burns of limited extent, early excision of the burn wound with immediate allografting can achieve early wound closure, result in shortened hospitalization and maximize functional recovery. The role of

### Table 1

EARLY EXCISION AND GRAFTING
(CATEGORY 2)

| *Age* | *Sex* | *% BSA* | *1st Grafting Day* | *No. Ops* | *Discharge Day* | *Complications* |
|---|---|---|---|---|---|---|
| 68 | M | 10 | 4 | 3 | 51 | primary graft failure |
| 24 | M | 2 | 2 | 1 | 9 | none |
| 22 | F | 20 | 4 | 1 | 19 | contracture, 1 finger |
| 50 | M | 10 | 4 | 3 | 31 | none |
| 56 | F | 10 | 5 | 2 | 51 | contracture, neck |
| 77 | M | 4 | 2 | 1 | 10 | none |
| 17 | M | 2 | 3 | 2 | 33 | partial graft failure |
| 10 | M | 1 | 1 | 1 | 2 | none |
| 55 | M | 85 | 3 | 1 | 7 | death |
| 35 | F | 6 | 2 | 1 | 13 | none |
| 2 | M | 25 | 2 | 1 | 15 | none |
| 19 | M | 1 | 3 | 1 | 5 | none |
| 55 | M | 1 | 4 | 1 | 12 | none |
| 52 | M | 10 | 2 | 1 | 4 | none |
| 48 | F | 10 | 5 | 1 | 16 | none |
| 73 | F | 2 | 4 | 2 | 17 | partial graft failure |
| 10 | M | 3 | 2 | 2 | 21 | partial graft failure |
| AVERAGE | | | | | | |
| 39 | | 12 | 3 | 1.5 | 19 | |

### Table 2

TOPICAL THERAPY, DEBRIDEMENT, DELAYED GRAFTING
(CATEGORY 3)

| *Age* | *Sex* | *% BSA* | *1st Grafting Day* | *Reason for Delay* | *No. Ops.* | *Discharge Day* | *Complications* |
|---|---|---|---|---|---|---|---|
| 32 | F | 7 | 11 | delayed transfer (5) | 1 | 23 | none |
| 49 | F | 10 | 15 | depth of burn underestimated | 1 | 33 | contracture axilla |
| 26 | M | 30 | 54 | delay transfer, sepsis diabetes, neuropathy | 1 | 65 | sepsis |
| 75 | M | 40 | 28 | COPD, recent MI, CVA | 3 | 43 | sepsis, MI, death |
| 66 | F | 35 | 16 | alcoholism, cirrhosis diabetes | 2 | 75 | asperation, death |
| 20 | F | 9 | 16 | delayed transfer (10) | 1 | 22 | none |
| 46 | F | 25 | 31 | patient choice | 1 | 48 | none |
| 48 | M | 10 | 16 | delayed transfer (4) infected burn | 2 | 41 | partial graft failure |
| 65 | F | 10 | 16 | surgeons choice | 1 | 25 | none |
| 62 | F | 12 | 16 | alcoholism, DTs | 3 | 45 | contracture arms & finger |
| 23 | M | 1 | 11 | contaminated wound | 1 | 16 | minor contracture fingers |
| 39 | F | 1 | 6 | delayed transfer infected | 1 | 17 | none |
| 52 | M | 1 | 7 | delay adm (3) | 1 | 18 | none |
| 17 | F | 12 | 9 | delay transfer (4) | 1 | 28 | none |
| 44 | F | 10 | 8 | delay adm (2) alcohol | 1 | 27 | none |
| 60 | M | 10 | 24 | cachexia, chemotherapy for cancer | 2 | 81 | partial graft failure, pneumonia |
| 26 | F | 12 | 12 | suicide attempt drug abuse | 2 | 69 | partial graft failure |
| AVERAGE | | | | | | | |
| 44 | | 14 | 17 | | 1.5 | 40 | |

surgical excision for more extensive burns has been controversial.

With the development of effective topical therapy, the trend until recently has been towards prolonged use with gradual wound debridement until the wound was "suitable for grafting." This is effective treatment, but leaves the patient with an open, potentially infected painful wound requiring repeated nursing and therapist care. In addition, the catabolic stressful period is prolonged and the likelihood of functional and psychological disability is increased.

The technique of tangential excision has been proposed by Janzekovic,[1] Jackson,[2] Burke,[3] MacMillan,[4] Mahler[5] along with many others. We are persuaded by the literature and our own experience that early excision and immediate autografting achieves optimal results provided patients are properly selected and the hospital facilities and staff are prepared for it.

The decision for early excision and grafting does not revolve around whether the burn wound will eventually heal but rather which technique will optimize survival plus the functional and cosmetic result. We feel that any burn wound which is not expected to heal within fourteen to seventeen days should be managed by early excision and grafting unless there are medical factors which contraindicate early surgery.

In our series of patients with deep dermal or full thickness burn injuries, those who met the criteria for early excision and immediate grafting were ready for discharge on their nineteenth post burn day as opposed to the fortieth day for the delayed group. Only two patients in the early group developed any functional contracture and only one required revisional surgery. Our goal, therefore, in treatment selection is to avoid doing too much too early in the poor risk patient which may produce a life threatening surgical or anesthetic complication. Conversely, we much avoid doing too little, too late in the good risk patient as this may lead to hypertrophic scar, functional limitation, prolonged hospitalization and thereby cost.

## Summary

The recent two-year experience of the Burn Service at Hartford Hospital has been reviewed. During this time, a total of seventy-five patients required hospitalization for burns. Of these, forty-one did not require surgery. Thirty-four patients required skin grafting. Of these, seventeen patients lent themselves to early excision and immediate allografting. Seventeen patients, either because of the surgeon's choice, delayed transfer or because of associated medical conditions, were managed with topical therapy, conventional debridement and delayed grafting. Early excision and immediate allografting in selected patients minimized hospital stay and produced optimal cosmetic and functional results.

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# Intussusception in Adults

HENRY MANNIX, JR., M.D. AND FAYYAZ HASHMI, M.D.

**ABSTRACT—Intussusception in adults is an uncommon cause of intestinal obstruction. In these patients, the majority will have a pathologic cause for the condition so that surgery is usually necessary. A review of 12 adults with intussusception seen in a community hospital over a twelve-year period is presented. The symptomatology varied, but certain symptoms such as abdominal pain, were commonly encountered. All but one patient was treated surgically. A more detailed analysis of two patients treated recently indicates the diversity of symptoms and the need for considering this entity in patients with intestinal obstruction.**

Intussusception is one of the most common causes of acute abdominal conditions in the pediatric population, ranking second only to acute appendicitis. It comprises 80% to 90% of intestinal obstruction occurring in children up to 14 years of age.[1] However, it constitutes only approximately 5% of mechanical obstruction in the adult population.[1 2 3] It accounts for approximately 0.1% of all adult hospital admissions.[3] Intussusception is much more commonly found in adults in certain parts of the world. In Korea, Southern India, and Western Nigeria, it constitutes 40% of all obstruction.[4] While approximately 90% of patients in the pediatric age group have no organic cause for the intussusception, the adult patient in the 65% to 85% of cases can be shown to have distinct pathology causing the condition.[1-6] In a review of 160 cases of adult intussusception reported from Louisiana State University School of Medicine, 84 were colonic and 76 occurred in the small bowel.[2] Definite pathology was identified in 49 of the 76 patients with enteric intussusception and in 69 of 84 patients with colonic type. The overall malignancy associated with intussusception ranges from 19% to 42% with higher incidence in colonic type where it is 54% according to most authors.[5] However, Smith and Gillespie reported an incidence of idiopathic intussusception in adults in 50% of their 34 patients in Glasgow.[6] More recently Murdock and Wallace reported 48% idiopathic intussusception in 16 patients encountered in Glasgow from 1968 to 1974.[7] The present report consists of 12 adults with intussusception encountered over a 12-year period. There were seven females and five males, ages ranging from 27 to 76 with a median age of 50.5. Eleven cases were primarily enteric, while one was primarily colonic. (Table I)

Table I

TYPE & LOCATION OF INTUSSUSCEPTION

| | | |
|---|---|---|
| Enteric | Jejuno-Jejunal | 7 |
| | Ileo-Ileal | 2 |
| | Ileo-Colic | 2 |
| Colonic | Colo-Colic | 1 |
| Total | | 12 |

## Clinical Findings

Most of the patients were admitted with acute or subacute abdominal problems. This includes ten of the twelve patients (Table II) of which seven were admitted with intestinal obstruction, two with an acute inflammatory abdominal process, and one patient admitted in the last trimester of her second pregnancy with intermittent epigastric pain, vomiting, and a previous three-month history of similar complaints. Because of the diversity of presenting

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symptoms, two representative cases will be outlined briefly.

## Case Reports

Case #1—B.R., 26-year-old female. This patient was transferred to Saint Francis Hospital and Medical Center with a diagnosis of midtrimester pregnancy complicated by presumed severe pancreatitis. On admission, she was acutely ill. Her serum amylases were elevated and ultrasound exam was interpreted as showing a pancreatic pseudocyst. She was treated conservatively and had one episode of upper GI bleeding. Many x-ray and laboratory tests were performed, but did not include a GI series. After six weeks of therapy with hyperalimentation and nothing by mouth, she improved and was discharged. Six weeks later, she was readmitted with similar symptoms. Pancreatitis was again considered as the diagnosis, but serum amylases were all normal. She did not repsond to treatment and a Cesarean section was carried out with the hope that the pancreatitis might subside. At laparotomy, the pancreas seemed normal and there was no evidence of intussusception. Six days post-Cesarean section, the patient developed an acute surgical abdomen. Peritonitis was clinically present and prompt laparotomy was performed. A double jejunojejunal intussusception with bowel perforation was found. No organic cause for the intussusception was found. Small bowel resection with end-to-end anastomosis was carried out. Her postoperative course was complicated by a probable pulmonary embolus, but she recovered and has been well over the last year. In retrospect, too much reliance was placed on the ultrasound diagnosis of pancreatic cyst.

Case #2—J.E., 34-year-old male. This patient presented to the Emergency Room complaining of abdominal pain, distention, vomiting, and passing blood per rectum. On physical examination, the patient clinically was obstructed. The admitting resident was suspicious of intussusception and ordered a barium enema, which clearly showed an ileocolic intussusception. (Figure 1). The patient was hydrated, electrolytes corrected, and a right colectomy and small bowel resection performed the afternoon of admission. The pathology was read as adenomatous polyps of the small and large bowel. Because of multiple colon polyps on follow-up barium enema, the patient subsequently had a subtotal colectomy with ileoproctostomy. The pathology on the colon specimen was that of hamartomatous polyps. His postoperative course also has been uneventful in the last four months. He is an example of the Puetz-Jegher syndrome.

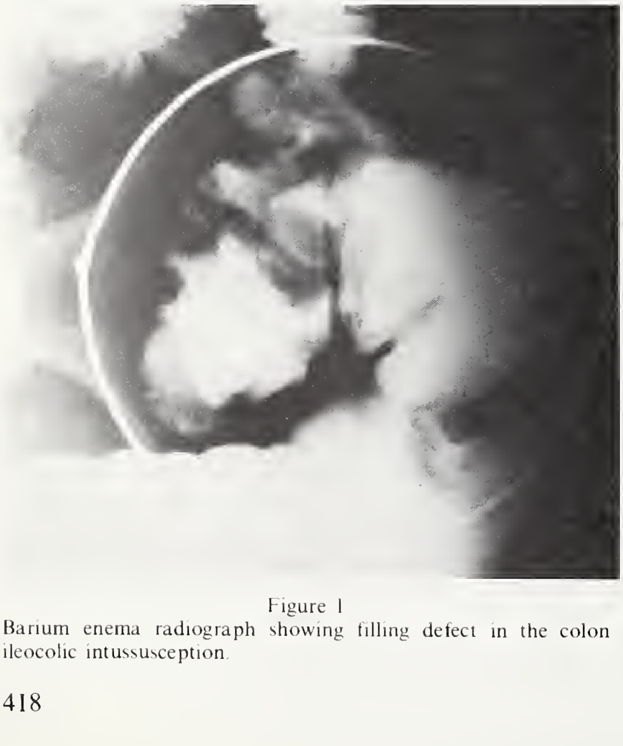

Figure 1
Barium enema radiograph showing filling defect in the colon ileocolic intussusception.

## Results

As can be seen from Table II, abdominal pain, nausea and vomiting were the presenting complaints in eleven of twelve patients. In addition, abdominal distention suggested intestinal obstruction in six of the patients and several patients were febrile. Three patients had a palpable mass and one patient had evidence of emptiness in the right lower quadrant. As shown in Table III, intussusception was secondary to benign tumors in four cases, malignant tumors in two, postoperative adhesions four, and three cases were idiopathic. The benign tumors included two lipomata, one adenomatous polyp and one Peutz-Jegher syndrome. The malignant lesions were adenocarcinoma of colon and bronchogenic carcinoma metastatic to ileum causing intussusception. DeCastro et al, reviewing metastatic tumors in small bowel in 101 patients, found only three instances associated with intussusception in adults.[8] Two were secondary to metastatic malignant melanoma and one due to metastatic carcinoma of the anal canal. Of the twelve patients, eleven were treated surgically. (Table IV). The one exception was a 50-year-old, white female admitted with a history of intermittent crampy abdominal pain, vomiting and distention. Flat film was suggestive of small bowel distention. A barium enema was done which revealed an intussusception of the ileocecal area which reduced without difficulty. Three patients had simple reduction, while eight had resection of small and/or large bowel. Six of the eight patients where resection was done had intrinsic pathology of the small or large bowel. The followup

Table II

CLINICAL PRESENTATION

| | |
|---|---|
| Abdominal Pain | 11 |
| Nausea/Vomiting | 11 |
| Distention | 4 |
| Diarrhea | 1 |
| Bleeding/Rectum | 1 |
| Fever | 5 |
| Localized Tenderness | 4 |
| Mass | 3 |

Table III

ETIOLOGIC CLASSIFICATION

| *Tumors* | *Enteric* | *Colonic* |
|---|---|---|
| Benign | 4 | |
| Malignant | | 1 |
| Metastatic | 1 | |
| Idiopathic | 3 | |
| Postoperative | 4 | |
| Total | 11 | 1 |

Table IV

TREATMENT & RESULTS

| | |
|---|---|
| Operative | |
| Resection | 8 |
| Simple Reduction | 3 |
| Non-Operative | 1 |
| Total | 12 |
| Death | 3 |

of these twelve patients reveals that the one patient who was not treated surgically was lost to followup. Eight of the eleven patients had an unremarkable postoperative period. There were three deaths. One patient, a 76-year-old man, who had a carcinoma of the cecum with significant atherosclerotic heart disease, developed cardiac and renal failure and died on his ninth postoperative day. A second patient, a 50-year-old female, with a history of previous myocardial infarction had resection of the terminal ileum and cecum. She dehisced her abdominal wound, aspirated during the second operative procedure, and died of cardiac arrest two days postoperative. The final death, a 44-year-old white female with bronchogenic carcinoma of the lung metastatic to the abdomen developed pleural effusion and died four days postoperatively.

## Comment

To see twelve patients with intussusception in a twelve-year period in a community hospital is unusual. All were proven either radiographically or at surgery. The diversity of clinical picture was quite striking. This was emphasized in the two cases that were presented in some detail. Since adults usually have an organic cause for the intussusception, it is less likely then that a barium enema will be successful in reducing the intussusception, although in one case this was accomplished. It is possible that one of the three deaths was preventable, since the dehiscence significantly contributed to the patient's death. The other two deaths appear to be non-preventable. There is evidence from this, as well as the literature, to indicate that while intussusception is much more common in children, it is an important cause of intestinal obstruction in the adult population, and if the physician is alert to the problem, the diagnosis may well be made preoperatively and the definitive operation carried out promptly. On other occasions, it is somewhat more difficult and only careful followup on the patient will give a good result.

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# Diastolic Murmur in a Patient with Complete Heart Block

EDWARD A. LONGO, M.D.

**ABSTRACT—A patient who developed a diastolic heart murmur during an episode of complete heart block is presented. There is no echocardiographic evidence of mitral stenosis as the etiology of the murmur and it disappeared after the insertion of a permanent pacemaker. A brief discussion is given as to the possible causes of this physical finding.**

Many abnormalities of heart sounds have been described in patients with complete heart block. Among these are: variable intensity of the first sound, splitting of the second sound, a systolic murmur of varying intensity, systolic ejection murmurs of aortic or pulmonic origin and atrial sounds occurring during ventricular diastole.[1, 2]

I recently had the opportunity of observing a patient with complete heart block who had a soft, low pitched, rumbling murmur occurring during ventricular diastole and coincident with P waves on the electrocardiogram. After the insertion of a pacemaker the murmur disappeared, and subsequent echocardiographic evidence was obtained which did not reveal any evidence of mitral valvular abnormality.

## Case Report

An 85-year-old female was admitted to the Intensive Care Unit at the Middlesex Memorial Hospital because a routine examination revealed a slow heart rate, between 30 and 50 beats per minute. The patient denied syncope and there was no history of rheumatic fever. Examination of the heart revealed cardiomegaly, a harsh, loud systolic murmur at the apex and an intermittent apical diastolic rumbling murmur which coincided with P waves on the monitor oscilloscope. Phonocardiography confirmed these findings (Figure 1). $M_1$ was not accentuated and no opening snap was heard. An electrocardiogram showed complete heart block with a ventricular rate between 30 and 50 beats per minute, and relatively narrow QRS complexes suggesting that the intrinsic pacemaker was in the bundle of His. An artificial pacemaker was inserted with good capture of the ventricle, and the diastolic murmur disappeared. Several months later, when echocardiography became available at our institution, this examination was performed, (Figure 2) and it revealed no evidence of mitral stenosis.

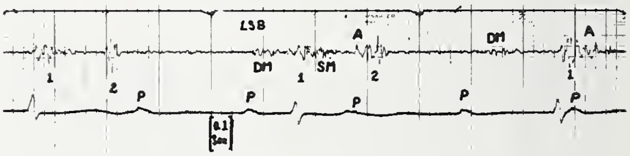

Figure 1
Phonocardiogram taken during the time patient was in complete heart block and prior to pacemaker insertion.

The tracing shows a low pitched, diastolic murmur (D.M.) occurring shortly after the onset of the P waves of the electrocardiogram. Note that the first P wave which occurs early in diastole is not accompanied by a murmur. When the P waves occur later in diastole the murmur becomes distinctly louder. In addition, there are low frequency vibrations (A) which occur in systole and also have their onset shortly after the P waves.

LSB = Left sternal border
SM = Systolic murmur

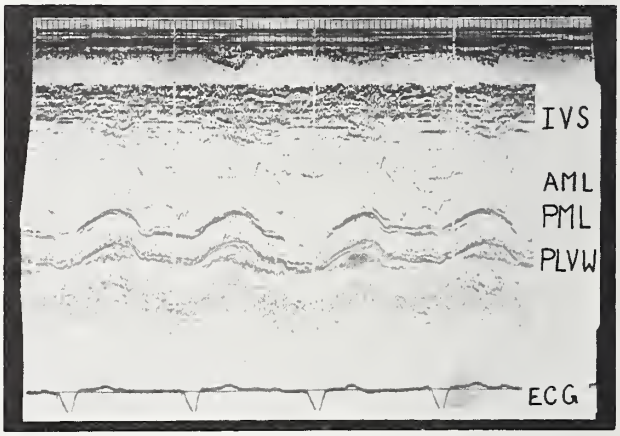

Figure 2
An echocardiogram obtained after pacemaker insertion showing normal motion of the leaflets of the mitral valve. Specifically, there is no paradoxical motion of the posterior mitral leaflet during diastole, and the E-F slope is not diminished.

IVS = Interventricular septum
AML = Anterior mitral leaflet
PML = Posterior mitral leaflet
PLVW = Posterior left ventricular wall

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## Discussion

In 1946, Rytand reported nine patients with complete heart block who had atrial sounds or murmurs occurring during ventricular diastole.[3] In those patients who developed atrial fibrillation, the fourth sound or atrial murmur disappeared, which indicated that the murmur was in some way related to atrial contraction. Since that paper was written prior to the advent of artificial pacing, the author had the opportunity to observe these patients for a prolonged period of time. He could not find clinical evidence of rheumatic mitral stenosis, such as opening snap or increased intensity of the first heart sound, but in four cases there was x-ray evidence of calcification of the mitral annulus. One patient came to autopsy and there was no evidence of mitral valvular disease. In contrast to the patient presented herein, it was noted that the murmur in his cases was loudest at the end of the early rapid filling phase of the left ventricle, whereas earlier or later in diastole the murmur was fainter.

The murmur in this case intensified late in ventricular diastole rather than during the rapid filling phase of the ventricle. When atrial contraction occurred in systole, low frequency vibrations were seen on the phonocardiogram. However, they could not be heard on auscultation.

The hemodynamics in complete heart block were described in a paper by Lind et al.[4] They found that the amount of blood flowing across the mitral valve is maximal during the early rapid filling phase and decreases thereafter throughout the remainder of diastole regardless of the presence or absence of atrial contraction. Atrial contraction during ventricular systole failed to open the mitral valve, causing a reflux of blood into the efferent pulmonary veins. Echocardiographic data in patients with complete heart block indicate that the anterior mitral leaflet moves posteriorly to its closed position shortly after atrial systole and remains in that position despite the long delay until the next ventricular systole.[5] This study also indicated that most of the flow across the mitral valve in complete heart block occurs early in diastole especially when atrial contractions occur during that time. Less flow occurs as diastole progresses.

The etiology of the diastolic murmur and of the low frequency atrial vibrations during ventricular systole is uncertain, but in this case report mitral stenosis was ruled out by echocardiography. The diastolic murmur could be the result of atrial contraction occurring at a time when ventricular filling has already occurred and the mitral valve is in its closed or nearly closed position, and this would be especially true as diastole progressed. This might be termed a "relative" or "functional" mitral stenosis. The low frequency vibrations occurring during ventricular systole might be due to atrial contraction against a closed mitral valve causing either rapid distention or vibrations in the efferent pulmonary veins and walls of the atrium during the period of reflux described by Lind et al. This latter mechanism might be operative during ventricular diastole as well.

It is hoped that this report will add to the impression that all diastolic murmurs are not necessarily due to organic valvular disease and will encourage more careful auscultation and study of patients in complete heart block.

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# Carcinoma Arising from Fistula in Ano

P. SIDDHARTH, M.D., WILLIAM KAISER, M.D., AND R. THORN, M.D.

**ABSTRACT—A case of a 59-year-old man who presented with perianal abscess, underwent incision and drainage and multiple biopsies of fistula in ano for 4 years before an adenocarcinoma was finally shown. GI workup including sigmoidoscopy and multiple random biopsies of rectum were negative. An abdominal-perineal resection was done.**

**There are various theories as to the origin of this tumor, namely, anal ducts and intramuscular anal glands, reduplication of intestinal tract, chronic inflammatory tract. Patients with repeated attacks of perianal abscesses should have deep biopsies of the perianal region.**

Carcinoma arising in fistula in ano is a rare lesion, the origin of which is still obscure. Unless several deep biopsies are taken the diagnosis is apt to be missed, with consequent delay in definitive treatment.

## Case Report

A 59-year-old black male correction officer was admitted to the VA Hospital Northport in October 1977, with pain and swelling in the perianal area of seven days' duration. Past history included repeated admissions to the hospital for perineal abscesses and fistula in ano since 1973. There was no history of cancer in the family. This patient had incision and drainage of the abscesses and excision of the fistula done in 1973, 1974, 1975, 1976 and 1977. On this admission the patient presented with a tender and boggy swelling in the left rectal wall. Temperature on admission was 38°C and the total white count was 15,000. There were several scars in the perineal area with tissue resembling granulation tissue in the scar. An incision and drainage was done and multiple deep biopsies were taken. The biopsy was reported as adenocarcinoma. Metastatic and G.I. work-up consisting of upper GI series, BA enema, liver scan, and colonoscopy was negative. CEA was 9.5 NG/ml. Repeated sigmoidoscopy and colonoscopy were done and random biopsies of the rectal and anal mucosa did not show any evidence of carcinoma. An abdomino-perineal resection was subsequently performed. Post-operatively the patient did well and returned to work. At 9 months' follow-up there was no evidence of metastasis.

### Pathology

Tissues submitted from fistulectomies previous to 1976 showed only abscess fibrosis and inflammation, but no epithelium. The fistulectomy performed in the early part of 1976 showed anal submucosal fibrosis, inflammation, and sinus tract lined by secretory epithelium disposed in single layers. The epithelium looked mature and was not characterized by atypia, interpreted as implanted colonic epithelium.

The tumor-bearing specimen consisted of an anus and surrounding soft tissues which showed a shaggy sinus tract originating at the anal verge. The tract measured 1 cm in diameter and was 3.5 cm long. The perianal tissue was nodular and firm to palpation. Microscopically the tract showed a papillary neoplastic lining composed of atypical columnar cells. Occasional mitosis and mucin production were observed in the cells. Large cystic areas containing mucin and surrounded by connective tissue were seen. Within the mucin pools were small islands of epithelial cells, some containing cytoplasmic mucus. Because of the above features, the diagnosis of perianal mucinous adenocarcinoma was made.

## Discussion

Perianal adenocarcinoma must be suspected in patients who have repeated episodes of perianal or perirectal abscesses. At the time of incision and drainage multiple deep biopsies of the buttock should be done. Nielson and Koch[7] postulated that these tumors arise from anal ducts and intramuscular anal glands which are found at the base of crypts of Morgagni. Anal ducts are tubular structures contiguous with the crypts of Morgagni and have been described by various investigators.[2 4 5 10] These are tortuous ducts whose distal portions are lined by a double layer of columnar epithelium, 6-8 in number, extending from the crypts to submucosa, perirectal fat and ischiorectal fossa.

Duke and Galvin[1] believe that these tumors arise from a malformation, i.e., reduplication of the intestinal tract. They reported two cases where muscularis mucosa was seen in the microscopic sections of the ducts.

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Some others[6] [9] have theorized that trauma induces squamous metaplasia which later leads to new growth formation just as malignant tumor can occur in association with chronic inflammatory tract or abscesses.

Prioleau[8] recently reported two cases both of which the tumor did not involve the anal ducts or the rectal mucosa. Whether the tumor arose from the fistula after it was formed or the abscesses were secondary to the tumor is not known. In the present case, repeated biopsies done before 1977 did not show any evidence of dysplasia or anaplasia and the patient presented himself 4 years before carcinoma was seen in the biopsy. Given that this is an adenocarcinoma, known to grow very slowly, it is our feeling that the tumor arose from anal duct columnar epithelium and over a time produced the fistula with which the patient presented. In view of the amount of fibrous tissue that may be associated with this tumor and difficulty in obtaining adequate tissue, it is emphasized that deep biopsies of the fistula be done on cases of recurrent fistulae and perianal and perirectal abscesses.

## Summary

A case of perianal adenocarcinoma is presented which was incidentally diagnosed by biopsies done at the time of drainage of the abscess. Several biopsies done previously did not reveal any evidence of malignancy. A brief review of literature as to the origin of this tumor is presented, and it is emphasized that deep biopsies of the buttock be done on cases of recurrent fistula in ano and perianal or perirectal abscesses.

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Most of the agitation regarding the high cost of medical care has been voiced by public health officials and members of foundations most of whom do not have a medical degree, much less any actual first-hand experience with what the practice of medicine and the relation of doctor to patient mean.—Quoted from letter of Dr. Harvey Cushing to Frances Perkins, Secretary of Labor, 1934.

# Gallstones, Pregnancy and Ultrasound

CASPER S. DE GRAAFF, M.D., AND MICHAEL CRADE, M.D.

**ABSTRACT—Three cases of cholelithiasis during pregnancy which were diagnosed by ultrasound are presented. Because of the lack of radiation and its high diagnostic accuracy, ultrasonography is the diagnostic tool of choice in the pregnant patient presenting with complaints suggestive of cholelithiasis.**

## Introduction

Conventional radiologic methods such as oral cholecystography (OCG) and intravenous cholangiography (IVC) are highly accurate procedures, but false negative results do occur. Ultrasonography is a useful complementary procedure, with an accuracy of approximately 91%.[2 6 9] When radiological methods are contraindicated by allergy to contrast medium, deep jaundice or by pregnancy, grey-scale ultrasonography is the method of choice in the diagnosis of biliary tract disease. Three case reports illustrate this use.

## Case Report #1

A 22-year-old, gravida 1 para 0, presented with a 5-month gestation and 2-month history of epigastric and right upper quadrant pain, with an acute exacerbation on the night of her emergency admission. Physical examination revealed only severe abdominal tenderness, no rebound was elicited and no masses palpated. Laboratory investigations revealed a serum amylase level of 5150 u/dl, and a serum lipase of 66 u/ml. Ultrasound examination demonstrated gallstones. A presumptive diagnosis of gallstone pancreatitis was reached and was not confirmed by any radiological procedures. After conservative medical therapy, surgery was performed and the diagnosis of gallstones was confirmed.

The patient was discharged fourteen days after admission with her pregnancy progressing normally.

## Case Report #2

A 28-year-old, gravida 2 para 1, presented at 28 weeks gestation with severe right upper quadrant pain. Laboratory values were normal. Emergency ultrasound examination demonstrated definite gallstones. An oral cholecystogram examination was not performed. This patient responded to conservative therapy and low fat diet. Three months after a normal delivery her abdominal pain recurred. Surgery performed at that time revealed gallstones and chronic cholecystitis.

## Case Report #3

A 17-year-old woman, approximately 23 weeks pregnant by dates, was admitted to Yale-New Haven Hospital complaining of several episodes of right upper quadrant pain for 3-4 days, accompanied by nausea and vomiting. The patient had no history of fatty food intolerance, liver disease or previous gallbladder disease.

On admission, a malnourished young woman was seen, in no acute distress. Physical examination revealed a pregnant uterus and a palpable mass in the right upper quadrant. Laboratory data revealed a white blood count of 18,100. Further laboratory results were unremarkable. An ultrasound examination revealed a right hydronephrosis and cholelithiasis. During scanning it was noted that the maximum tenderness overlaid the gallbladder. The patient was treated conservatively and her symptoms gradually subsided. She was discharged with her pregnancy progressing normally. No elective surgery was performed after her delivery by caesarean section, although the patient still complains of fatty intolerance.

## Discussion

Many papers have been published recently about the causes of gallstone formation, but the true mechanism of gallstone formation has not been defined completely.

Elevated estrogen levels appear to increase the lithogenic tendency of bile, thus increasing the risk of stone formation.[1 3 8 10] Interestingly, an association between gallbladder disease and birth control pill use, as well as postmenopausal estrogen use has been made.[4 5] The elevated estrogen levels of pregnancy could be reasonably expected to produce similar results.

An accuracy of 91% has been documented for gallstone diagnosis by grey scale ultrasound.[9] When shadowing opacities that move with gravity are seen within the gallbladder lumen a diagnosis of gallstones is virtually certain (Figure 1).[6] False-positive examina-

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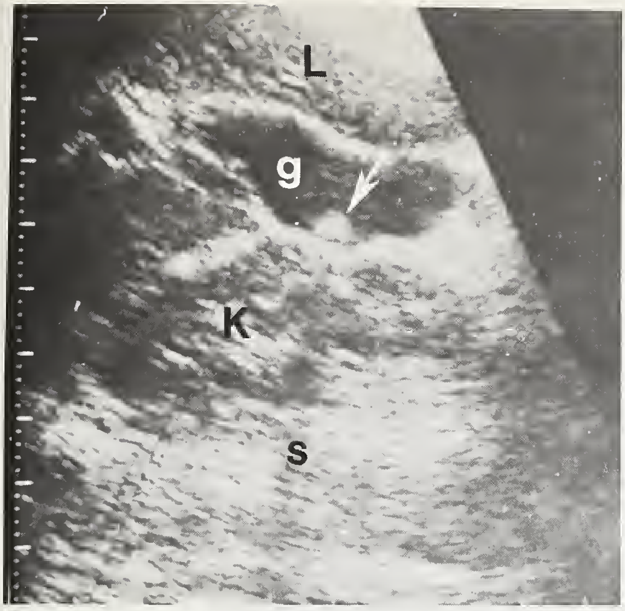

Figure 1
The typical appearances of gallstones are demonstrated in this scan. Opacity (arrowed) with distal shadowing (s) is seen in the well defined gallbladder lumen (g). Liver (L) and right kidney (K) are also seen on this longitudinal scan. Findings are virtually diagnostic of gallstones.

tions are extremely rare and most errors are false-negatives due to the tomographic nature of the technique. In our experience there have been no false-positive examinations in cases where the typical gallstones appearances are seen with evidence of distal shadowing and movement with gravity, such as in case #3. Furthermore, we have found cholelithiasis on ultrasound examination when the oral cholecystogram was falsely normal.[7] Although oral cholecystography is known as a highly accurate diagnostic tool, several problems have been encountered. Among these problems are the nonvisualization of the gallbladder due to malabsorption and liver disease. Another problem to be avoided especially in pregnancy, is radiation exposure. We therefore suggest that ultrasound be considered the modality of choice in the diagnosis of gallstone disease during pregnancy.

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# Gallstone Pancreatitis in Four Connecticut Hospitals: 1977-1978

DR. HASTINGS K. WRIGHT (Chief of General Surgery, Yale-New Haven Hospital): Patients being treated for acute pancreatitis account for approximately 1% of all hospital days in Connecticut in the past decade. Most such patients have relapsing pancreatitis 2° to alcohol abuse or other causes of small duct obstruction in the pancreas. Their treatment is not surgical unless complications of pancreatitis develop such as pseudocysts or pancreatic necrosis. However, 15-20% of patients are admitted to the hospital with acute pancreatitis 2° to obstruction of the main pancreatic duct by gallstones. Their treatment should be surgical.

While gallstone pancreatitis is usually said to be benign and short lasting, it has been recently shown in retrospective studies at Yale that this is not necessarily so. Gallstone pancreatitis can go on to all the complications of small duct pancreatitis, and lead to death. Accordingly, it is important to differentiate between alcoholic or small duct pancreatitis and gallstone pancreatitis and perhaps to operate quickly on gallstone pancreatitis. The question we have asked our panel today is how to differentiate between these two groups of pancreatitis. In addition, there are evolving opinions about *when* one should operate on patients with gallstone pancreatitis. The dictum in the 1950's was that all such patients should be allowed to undergo resolution of the pancreatitis prior to any definitive biliary tract surgery. Is this dictum no longer true?

The surgical services at the Milford Hospital, Lawrence & Memorial Hospital in New London, the Danbury Hospital and the Yale-New Haven Hospital have searched retrospectively for the past two years to find all patients admitted to the hospital with pancreatitis and then reviewed carefully all cases of gallstone pancreatitis. What studies were done and when after the admission of the patient for pancreatitis? When was operation performed? What operations were done? The rate of gallstone pancreatitis in this two-year period is recorded in Table I.

Table I

PANCREATITIS SECONDARY TO BILIARY TRACT DISEASE IN FOUR CONNECTICUT HOSPITALS 1977-1978

| *Total Admissions for Acute Pancreatitis, All Causes* | *Cause Found to be Biliary Tract Disease* |
|---|---|
| 319 | 45 (14%) |

The mortality rate for patients undergoing surgery was 5%. The two patients who died were both patients in their eighth decade, and both died of postoperative cardiopulmonary complications. No patient who underwent surgery for gallstone pancreatitis went on to develop hemorrhagic pancreatitis or major complications of pancreatitis such as necrosis or pseudocyst formation.

The average time from admission to the hospital to operation for patients discovered to have gallstone pancreatitis was 7.5 days. Only 11% of the patients discovered to have gallstone pancreatitis were not operated on during the initial admission for pancreatitis, and these patients all underwent elective biliary tract procedures within six weeks.

Table II shows the findings at surgery. 98% of patients were found to have gallstones in the gallbladder. 28% had stones in the common duct at surgery. In 90% of the cases, the correct diagnosis had been made preoperatively either by intravenous cholangiography or by ultrasound.

Table II

FINDINGS AT SURGERY IN 40 PTS. OPERATED ON ACUTELY DURING THE PANCREATITIS

| *Stones in Gallbladder* | *Stone in Common Duct* |
|---|---|
| 39 (98%) | 11 (28%) |

---

A panel discussion at Surgical Grand Rounds, Yale-New Haven Hospital, February 3, 1979.

In all but one case, a definitive biliary tract procedure was performed. In one case, a cholecystostomy was performed in a patient with severe decompensation. This patient later died.

The first question we would like to ask our panel is whether it is possible on clinical grounds alone to differentiate patients with a typical attack of pancreatitis into those with gallstone pancreatitis and those with small duct pancreatitis?

DR. NICHOLAS COASSIN (Chief of Surgery, Milford Hospital): I do not believe that it is possible to make a diagnosis on the basis of history alone. A certain percentage of patients with alcoholism will have gallstone pancreatitis as their first attack, and they cannot be eliminated from work-up. Accordingly, all patients with pancreatitis should undergo radiologic and ultrasonographic studies of their biliary tract. This should be done during the acute phase, accepting the fact that nonvisualization of the gallbladder on an intravenous cholangiogram or oral cholecystogram during the acute phase of pancreatitis does not make the diagnosis of gallbladder pathology. If the patient has rapidly resolving pancreatitis as is the rule in patients with gallstone pancreatitis, then I usually wait approximately a week before doing the radiologic studies.

DR. MALCOLM ELLISON (Chief of Surgery, Lawrence & Memorial Hospital): It is important to make a positive diagnosis of biliary tract calculi before operating in the acute phase on these patients, unless sepsis or hemorrhage forces the surgeon's hand. Fortunately, in the experience of the group as a whole, this was possible in almost 100% of patients who were operated on. The ultrasonography was positive in our own series over 90% of the time in patients with gallbladder calculi, and intravenous cholangiograms performed after the patient had resolved any jaundice associated with the pancreatitis were positive in every case where common duct stones were found at surgery.

DR. COASSIN: We have done a retrospective study at the Milford Hospital over the last ten years, and there is no doubt that our surgeons are now operating on patients with gallstone pancreatitis much earlier in the last five years than they were ten years ago. I believe the reason for this is that the advent of ultrasonography now has allowed us to make very accurate diagnoses in pancreatitis where previously the biliary tract could not be visualized due to jaundice or low-grade obstruction of the common duct. The old procedure was to allow the patient to recover from the episode of acute pancreatitis for a week to ten days in the hospital, and then to send the patient home for six to twelve weeks before doing a definitive work-up as an out-patient. Today a definitive work-up is performed within three or four days of admission of the patient with acute pancreatitis. If a diagnosis of biliary tract disease is made, the patient is operated on immediately.

DR. EDWARD FERNAND (Attending Surgeon, Danbury Hospital): We have had a number of patients who have had both acute pancreatitis and acute cholecystitis at the same time. In the last five years, with the diagnosis of gallstone pancreatitis having been made by sonography, we have not hesitated to operate on these patients within two or three days after admission to the hospital. In the past, our routine was to wait until the patient had recovered from pancreatitis and then to study the biliary tract by contrast techniques at a later time.

DR. NICHOLAS PASSARELLI (Assistant Chief of General Surgery, Yale-New Haven Hospital): In looking at the last 16 cases that we have operated on at the Yale-New Haven Hospital with gallstone pancreatitis, we found that in 12 of the cases sonography was accurate in making the diagnosis. However, in 4 cases the diagnosis of biliary tract pathology was made only after the pancreatitis had subsided and the patient had been studied with contrast media. Thus, one cannot rely totally on sonography in making a diagnosis. I do feel that when the sonographer is positive in his interpretation of the study in the acute phase, then it is extremely accurate.

DR. WRIGHT: The dictum a decade ago was that patients with small duct pancreatitis who were explored did poorly. Did anybody on the panel have this experience in his hospital?

DR. FERNAND: I pooled the members of the panel, and in only one case in the last two years did a patient with non-gallstone pancreatitis undergo early laparotomy. This patient was deteriorating and at surgery was found to have hemorrhagic pancreatitis. Surgeons are not operating in the face of pancreatitis without a positive indication that biliary tract disease indeed is present. Fortunately, the errors that are made with the present diagnostic techniques including ultrasound are not on the false-positive side, but on the false-negative side. What we have to worry about is how to diagnose patients with pancreatitis who actually have biliary tract disease in whom no positive diagnosis can be made with the presently available techniques.

DR. WRIGHT: That brings up the question of whether or not laboratory tests such as measurements of amylase and lipase and liver function studies can be used to differentiate patients with gallstone pancreatitis from patients with other causes.

DR. FERNAND: We have been impressed at the Danbury Hospital that in many cases of gallstone pancreatitis, the serum amylase goes far higher than in patients with small duct pancreatitis. In addition, the amylase tends to fall within two to three days to normal in patients who have gallstones.

DR. PASSARELLI: The study by Gliedman of over 2,000 patients with acute pancreatitis, of which approximately one fourth were caused by gallstones, showed that the amylase values were much lower in patients in the acute phase of small duct pancreatitis than in the acute phase of gallstone pancreatitis.[1] The other difference was that the elevation of amylase persisted for long periods of time in patients with small duct pancreatitis, in contrast to gallstone pancreatitis where the amylase came down very rapidly to normal. The explanation for this difference is not clear, but Dr. Howard Spiro at Yale has suggested that perhaps patients who have an acute attack of alcoholic or small duct pancreatitis already have a largely burned out pancreas and thus can't get their amylase values as high as those who have normal pancreases which are acutely inflamed secondary to blockage by gallstones. Unfortunately, there is enough overlap of standard deviations around these different averages so that in the individual case, one cannot rely on the height which the amylase value goes in differentiating between these two causes of pancreatitis.

DR. MORTON BURRELL (Chief of GI Radiology, Yale-New Haven Hospital): A new nuclear medicine technique is on the horizon now which employs imaging agents injected intravenously which are excreted by the liver into the biliary tract in high concentrations even in the presence of bilirubin concentrations above 3-5 mg%. The agent being used at Yale in a prospective study is HIDA, a radioactive-tagged diacetic acid derivative which is rapidly excreted by the liver into the biliary tree. The intrahepatic bile ducts are visualized on scanning within 15-20 minutes, and the common duct and gallbladder are visualized within 30 minutes, with the dye then seen in the GI tract within an hour. The early evidence from this institution and others indicates that this study is very accurate in making a diagnosis of acute cholecystitis when dye does not appear within the gallbladder itself within a period of 1½ to 2 hours. The appearance of the radionucleotide in the gallbladder does not depend on concentration of the agent by the gallbladder, but on direct excretion of the agent into the biliary tract and its entrance through a non-obstructed cystic duct into the gallbladder. The great advantage of the new technique is that it will allow us to study patients with possible acute cholecystitis during acute pancreatitis with jaundice when contrast media are not excreted into the biliary tract.

DR. WRIGHT: The last thing we will ask the panel is what should be done at the time of surgery in the patient with acute gallstone pancreatitis. Should a definitive operation be done, or should the operation be limited to drainage of the biliary tract and pancreas?

DR. COASSIN: There is no evidence from the present study in these four hospitals that there is any danger of doing a definitive operation to remove the gallbladder plus remove any calculi found in the common duct in the face of acute pancreatitis caused by gallstones. I should add that I have found it necessary in these patients always to do operative cholangiograms, a procedure I do not always do in patients who simply have acute cholecystitis without associated pancreatitis.

DR. ELLISON: A definitive operation should be done at the time of the initial exploration even in the face of acute pancreatitis. The only exception to this would be in patients where the anatomy is so obscured by the acute pancreatitis that a definitive procedure cannot be safely performed.

DR. PASSARELLI: I believe that even if one is unable to do a definitive procedure, one should at least provide drainage of the common duct in all of these patients. This cannot be accomplished safely by doing a cholecystostomy alone. A tube should be inserted into the common duct.

DR. WRIGHT: I would like to thank the panel for participating in this discussion and also particularly thank the surgical residents in these four hospitals who did much of the leg work in looking up the records of the 262 cases seen in this two-year period. Thank you.

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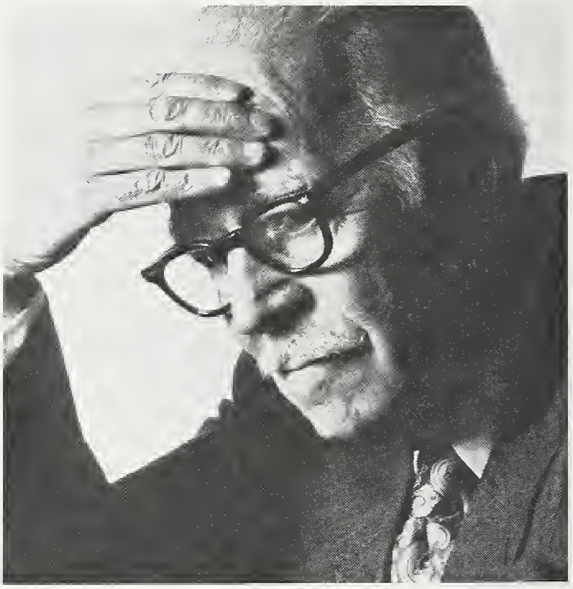

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CURRENT DRUG INFORMATION

*Moses Chow, Pharm. D., Consulting Editor*

# Guanidine

## A Review

M. J. SEVKA, PHARM. D.

Guanidine has been tested with variable success as a treatment for various neurological disorders since 1939 or earlier. Recognition of its true therapeutic value awaited more precise explanation of its mechanism of action and more detailed definition of neurologic disorders for which guanidine had potential use. Indeed, guanidine might be considered a classic example of a drug is search of a disease. Most notable is the use of guanidine in the treatment of Eaton-Lambert Syndrome, a neurologic disorder not described until the 1950's, and for which guanidine now has a clear use.

### Indications

Currently, guanidine is approved by the FDA only for the reduction of symptoms of muscle weakness associated with Eaton-Lambert syndrome. Because guanidine increases acetylcholine release at myoneural junctions, it has been tested in other conditions associated with acetylcholine disturbances: botulism and myasthenia gravis. Empirically, it has been tested in the treatment of amyotrophic lateral sclerosis. Guanidine is not approved by the FDA for the treatment of botulism, myasthenia gravis, or amyotrophic lateral sclerosis.

### Mechanism of Action

At the normally functioning myoneural junction, a presynaptic action potential following nerve stimulation results in the release of acetylcholine "packets" or transmitter quanta. Guanidine increases the efficacy of neuromuscular transmission by facilitating acetylcholine quantal release following a presynaptic action potential.[1] The proposed mechanism by which acetylcholine release is enhanced is as follows.[2] In the normal nerve membrane, calcium channels are thought to exist which permit an inflow of Ca++ during an action potential. Gating mechanisms for calcium channels open with depolarization resulting in increased intracellular Ca++ concentration and therefore greater quantal release. Guanidine, by screening fixed negative charges on the surface of presynaptic nerve membrane near the calcium channels, would reduce the effective potential difference across the membrane—in essence maintaining the channels in a more depolarized state. Therefore, following a nerve action potential, calcium channels would open sooner and stay open longer leading to increased Ca++ conductance and increased quantal release.

### Efficacy

Eaton-Lambert Syndrome (ELS): ELS is a myasthenic-myopathic state most often associated with small cell carcinoma of the lung. It is characterized by proximal muscle weakness and usually spares ocular and bulbar muscles. Typically, weakness improves with muscle contraction, is little effected by neostigmine, and easily exacerbated by tubocurarine and decamethonium. The basic junctional defect in ELS is decreased acetylcholine release from the nerve terminal following a motor nerve action potential.[3] This explanation is supported by the documented decrease in amplitude of the end plate potential (EPP) following motor nerve stimulation.[3] Acetylcholine production and end plate sensitivity are not diminished as manifested by normal miniature end plate potential (MEPP) recorded from the end plate region of single muscle fibers.[3] Consequently, cholinesterase inhibitors such as neostigmine, which do not increase acetylcholine release, may ameliorate muscle weakness of ELS only slightly, but guanidine which increases acetylcholine release, can be more effective.[4,5,6,8,10,12]

Guanidine appears to be effective clinically in relieving the symptoms of weakness associated with

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ELS.[4,5,6,8,10,11,12] The characteristic electromyographic changes that occur in ELS are 1) reduced muscle action potential amplitude following a single motor neuron stimulus 2) a reduction in muscle action potential amplitude following repetitive nerve stimulation at a low rate such as 2 per second and 3) an increase in muscle action potential amplitude following nerve stimulation at a rate higher than 10 per second.[4] Reversal of these electromyographic findings and clinical improvement of muscle strength with guanidine therapy has been reported in the majority of trial cases of ELS.[4,5,8,11]

Clinical improvement from guanidine may not be observed for 3 to 4 days following initiation of treatment[8] and discontinuation of the drug for brief periods has resulted in return of weakness.[5,6,10]

The usual recommended dose is 10 to 14 mg/kg/day (divided into three or four smaller doses) initially, gradually increasing to 35 mg/kg/day or up to the development of side effects.[25] Maximal improvement in strength may require higher doses, but have been associated with severe side effects.[5,8]

Botulism: Since botulinium toxin prevents acetylcholine release, guanidine has been tried in the treatment of botulism. Guanidine has been reported to be beneficial in at least 9 of 14 patients who received variable doses as high as 35 mg/kg/day.[13] Unfortunately, it appears to be useful in less severe cases and is not as effective in overcoming neuromuscular block of respiratory muscles as it is in limb and extraocular muscles.[13] Lack of benefit in the treatment of botulism has been reported also.[14,15] The exact status of guanidine in the treatment of botulism needs further investigation and delineation.

Amyotrophic Lateral Sclerosis (ALS): An empirical trial of guanidine in 24 patients with ALS at two dosing levels (1.5—2.5 mg/kg/day or 25 mg/kg/day) suggests that some modification of the disease course may be possible.[16] The group taking the higher dose had lower mortality and more stable disease after six months of treatment but after ten months, no patient showed any improvement.[16] Another study using 20 to 40 mg/kg/day also reported a diminution in the rate of progression of both ALS and degenerative diseases of the spinocerebellar system or peripheral nervous system.[17] Further investigation is needed to confirm these results.

Myasthenia Gravis (MG): Reports of guanidine efficacy in the treatment of muscle weakness of MG are contradictory. Minot et al reported favorable results in 5 of 7 subjects using doses up to 35 mg/kg/day, but some patients received concomittant neostigmine.[18] Another early report of clinical trials reported that guanidine increased the effect of neostigmine in 8 of 25 subjects, but the other 17 failed to respond.[19] These reports have been refuted by a more recent study reporting an increase in neuromuscular block and exacerbation of symptoms in 3 trial patients with severe disease taking up to 25 mg/kg/day.[20] In this trial, depletion of acetylcholine stores was suggested as a possible explanation for the increase in neuromuscular block.[20] Furthermore, previously reported favorable responses may represent trials in a myasthenic subgroup.[20] Guanidine is not recommended as a treatment modality especially considering that the neuromuscular defect in MG does not appear to be a defect in acetylcholine release.[20]

### Adverse Effects

Multiple adverse effects have been attributed to guanidine therapy—most important of which are hematologic. Anemia, leucopenia, and thrombocytopenia, have all been associated with guanidine therapy.[8,16,21,22] with the incidence of marrow depression estimated at 2.5%.[16] Four reports of apparent aplastic anemia have been mentioned.[9] Eosinophilia has also been observed.[16,21]

Interstitial nephritis has been reported in a 43-year-old man after 4 years of guanidine therapy (1500 mg-1825 mg/day)[10] and also in a 66-year-old man after 5 years therapy (1000 mg/day).[6] Five other patients who developed renal impairment have been mentioned.[7]

Induction of atrial fibrillation has been associated with an increase of guanidine dose to 21 mg/kg/day in a 70-year-old patient.[23] After discontinuation, a subsequent rechallenge with 21 mg/kg/day resulted in atrial fibrillation within 36 hours.[23]

GI side effects, including gastric irritation, nausea, diarrhea and abdominal cramping, may be of sufficient severity that therapy be terminated; such symptoms may be indicative of ensuing overdose.[25]

Finally, apparent dose related increases in muscle weakness accompanied the treatment of two oriental men with motor neuron disease.[24]

Additional adverse reactions include: paresthesia of the lips, face, hands and feet, nervousness, emotional lability, ataxia, psychosis, rash, purpura, sweating, palpitation, tachycardia, and hypotension.

### Availability

Guanidine is available as 125 mg tablets as the hydrochloride salt, from Key Pharmaceuticals.

### Summary

Guanidine is indicated in the treatment of muscle weakness in ELS. Though not approved for use, guanidine appears to be of benefit in less severe cases of botulism, and may be of some benefit in altering the progress of ALS. Guanidine does not have a role in the treatment of MG.

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## NUMBER OF UNITED STATES OPERATIONAL MEDICAL SCHOOLS, MEDICAL STUDENTS, AND MEDICAL SCHOOL GRADUATES

| | 1949-50 | 1959-60 | 1969-70 | 1976-77 |
|---|---|---|---|---|
| Medical schools | 79 | 85 | 101 | 116 |
| Total medical students | 25,103 | 30,084 | 37,669 | 58,266 |
| Women medical students | 1,806 | 1,710 | 3,390 | 13,059 |
| Total medical graduates | 5,553 | 7,081 | 8,367 | 13,607 |
| Women medical graduates | 595 | 405 | 700 | 2,611 |

Sources: Medical Education in the United States, 1962-63 and 1976-77, Chicago: American Medical Association.

From 1949-50 to 1976-77, the total number of medical students increased 132 percent. In the same period, the enrollment of women in the nation's medical schools increased more than seven-fold. In 1949-50, women represented 7 percent of the total number of medical students; by 1976-77 they represented 22 percent of the total. Women represented 11 percent of the graduates in 1949-50 and 19 percent of the graduates in 1976-77.—*Socio-Economic Factbook for Surgery, 1978.*

## Blue Cross and Blue Shield Associations Medical Necessity Project
## Procedures Requiring Satisfactory Justification

| Blue Shield Plan Code | Procedure Description | Reason(s) for Deletion |
|---|---|---|
| 8076 | Amylase, blood isozymes, electrophoretic | Not clinically useful |
| 8118 | Chromium, blood | No clinical indication |
| 8181 | Guanase, blood | Obsolete; liver enzyme determination more useful |
| 8357 | Zinc sulphate turbidity, blood | Obsolete; liver enzyme determination more useful |
| 8543 | Skin test, cat scratch fever | Deleted by Center for Disease Control, 1976; test material not available commercially. Diagnosis based largely on clinical situation |
| 8548 | Skin test, lymphopathia venereum | Nonspecific, positive with other Clamydial diseases. Complement fixation with heat stable group reactive antigen is best test available |
| 9440 | Circulation time, one test | Obsolete |
| 8102 | Cephalin Flocculation | Obsolete; liver enzyme determination more accurate |
| 8120 | Congo red, blood | Obsolete; replaced by rectal or gingival biopsy |
| 8240 | Hormones, adrenocorticotropin quantitative animal tests | Obsolete; radioimmunoassay more accurate and specific |
| 8206 | Hormones, adrenocorticotropin quantitative bioassay | Obsolete; radioimmunoassay more accurate and specific |
| 8334 | Thymol turbidity, blood | Obsolete; liver enzyme determination more accurate |
| 8540 | Skin test, actinomycosis | Deleted by CDC in 1976; diagnosis made by microscope identification of organism and positive culture |
| 8542 | Skin test, brucellosis | Deleted by CDC in 1976; diagnosis made by isolation of organism and suggested by presence of agglutinating antibodies |
| 8547 | Skin test, leptospirosis | Deleted by CDC in 1976; diagnosis made by isolation of organism and serologic studies |
| 8551 | Skin test, psittacosis | Deleted by CDC in 1976; diagnosis made by isolation of organism or four-fold rise in complement fixing antibodies |
| 8554 | Skin test, trichinosis | Deleted by CDC in 1976; diagnosis made by presence of larvae in muscle biopsy |
| 8601 | Calcium, feces, 24-hour quantitative | Obsolete; replaced by quantitative stool for fat |
| 8610 | Starch, feces, screening | Not informative; impossible to interpret |
| 8623 | Chymotrypsin, duodenal contents | Unreliable; replaced by secretin test |
| 8634 | Gastric analysis pepsin | Not informative |
| 8635 | Gastric analysis, tubeless | Not reliable |
| 8903 | Autogenous vaccine | Not proven value |
| 8376 | Calcium saturation clotting time | Obsolete; replaced by thromboplastin generation |
| 8377 | Capillary fragility test (Rumpel-Leede) (independent procedure) | Superfluous |
| 8643 | Colloidal gold | Obsolete; replaced by immunoelectrophoresis |

# The Spiralling Costs of Medical Care

## Solving the Problem: The Role of Government, Medicine and the Individual

(Second of Two Parts)*

HERBERT H. HYMAN, PH.D.

**In Part I, we discussed some of the major causes of the spiralling costs of medical care with the main focus on the increased use of medical technology. While physicians have been accused as the major cause of this increased emphasis on medical technology,, Part I showed that physicians represent only one component of a complex web of factors which have led to this outcome. Other major factors involved were shown to be heightened consumer expectations of the miracles medical technology was believed to perform at little or no cost to him/herself, the government's funneling of huge sums of money for bio-medical research, the competitive role of hospitals for leadership and status, and the training of physicians to the importance of medical technology. All of these factors interrelate to produce America's love affair with medical technology and the subsequently higher costs of medical care.**

In recent years, there has been a growing reaction to this emphasis and some disenchantment with medical technology. In Part II, we aim to explore the sources of this reaction, governmental efforts to deal with it, and a three pronged strategy involving medicine, the community, and the consumer to counter it.

### The Reaction: Why It's Coming Now

Reactions to medical costs emanate from two sources, national and international affairs affecting the American economy and the desire to brake the costs of care by some consumer elements exerting their influence on Congress and presidential politics. First, let us examine some of the forces at work on the national and international levels. Three forces have been at work and are now profoundly influencing the American economy. First, the oil embargo and the resulting energy crisis have dramatically escalated the costs of gas and oil. It has also increased our dependence on Arab and other oil producing nations. Forced to pay higher costs for energy, the average American has less money to spend for other needs.

The oil embargo triggered off a general recession mingled with inflation. Inflationary costs are wiping out any gains made by American workers and their unions. Union members have repeatedly rejected contracts negotiated by their leaders. Not only are they concerned about job security, but they want more take home pay to offset galloping inflation. When the union negotiators cast about for ways that can achieve this, one component of the wage package that comes to their attention is the amount of money allocated for health care insurance. They are targeting health care benefits because it is so visible and costly. The unions and the corporations are beginning to ask questions about these costs. There is even consideration on the part of some of our leading corporations to develop their own insurance plans in an effort to reduce the price of health care premiums. The once cozy relationship between many of these same corporate leaders as members of the leading hospital boards is putting a strain on them as they witness how their hospital decisions influence their own costs of doing business. They are consequently giving closer scrutiny to these decisions. The unions are simultaneously moving in two potentially opposite directions with respect to health care costs. On one hand they are pressing for a national health insurance plan that will raise costs, but shift them from the bargaining table to the government. On the other, they are becoming active in health planning agencies in order to press for those components of the plans that will reduce overall health costs, with special emphasis on making the hospitals more

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efficient in their use of facilities and equipment. In this regard, their focus is on medical technology and efforts to prevent its diffusion and unnecessary duplication.

The third force reacting to higher costs of health care is the public's general loss of credibility with the efficiency of government itself: federal, state, and local. The emphasis of the last presidential campaign and the current symptoms of a taxpayer's revolt, embodied in numerous defeats of local education budgets and in the passage of California's Proposition 13, are illustrative of this loss of trust. While many areas of high government expenditures are being examined, health care is one of the areas coming under close scrutiny. The public is particularly upset with sporadic reports citing higher than expected income for physicians under Medicaid payments, the ping-ponging of patients for profit, the charging for services never rendered, and the provision of services for which there is no medical problem. Pressure is brought to bear to put a ceiling on physician payments for services rendered as well as holding the line on publicly controlled expenditures in the operation of hospitals. In New York City, six to seven thousand beds have been closed in the municipal system in the past decade. This action would have been welcomed as an effort to reduce the number of excess beds, said to number 5,000 in New York City, except for the fact that an almost equal number of beds have been opened in the same period of time in the voluntary private sector. All that this does is raise questions by the public and by the citizens' bodies that monitor the health care field about the credibility of the leaders in the health care field and their apparent abuse of the public trust. Indeed, Roemer's principle says that in the health care field if there are empty beds they will be filled, whether services are truly needed or not.

Thus, these three external forces have upset the general American economy and brought concern to workers about their own job security and ability to earn enough income to maintain their standard of living. While there is general concern about government in general, there is particular emphasis on reducing the costs of health care, costs which are more and more being perceived as eating away at the take home pay needed by the average worker.

Internally, there has been a mixed picture of how valuable the use of medical technology really is. On one hand, there are those who raise questions about whether medical technology makes any difference at all in health outcomes.[1] There have been no appreciable reduction in either the morbidity or mortality rates in spite of the heavy investment in these innovations. Some have stated that the emphasis in NIH allocation of funds is misplaced. It is pointed out, for example, that "mental illness, which ranks third in cause of days of hospitalization and fourth in cause of limitation of activity, received only 6% of these outlays. Only 7% went for research on arthritis, metabolic and digestive problems, which together are the leading causes of days of hospitalization."[2] Furthermore, some have noted that the emphasis on research has deemphasized the treatment of the more common diseases and illnesses in community hospitals. As one investigator noted, "medical intervention has a significant effect on outcome in only a small fraction of the cases seen by the average physician."[3] Most illnesses are either self-limiting and require no medical treatment, or are chronic and thus incurable. Chronic illnesses require a physician to emphasize the "caring" rather than the "curing," an art that is rapidly being lost in the medical schools' love affair with technology.

On the other hand, there are those who point out the benefits of medical technology. The favorable benefit-cost ratio favoring the expenditure of millions on technology has already been noted. The CAT Scanner, for example, reduces both hospitalization costs and pain to patients treated with pneumoencephalography.[4] Another researcher noted that in 1970 alone, the application of 17 different medical inventions used in surgery for various diseases prevented the deaths of 65,000 persons who would have died had the technology not been used.[5] Furthermore, for nine different disease categories such as peptic ulcer, heart conditions, and hearing impairments, there have been significant improvements between the years 1961 and 1969 on three health indicators. With respect to limitation of a person's activity, there has been improvement in 8 of the 9 disease categories. In six of the nine categories, there have been fewer work days lost; and in all nine categories, there have been fewer cases of bed disability.[6] However, this same researcher notes that the prevalence of the diseases in the population have increased, in some cases dramatically, during the eight years. For example, the cases per 1,000 population show more than a 50% increase in prevalence of heart conditions, hypertension without heart involvement, arthritis and rheumatism, visual and hearing impairments. It is these statistics that provide ammunition to those opposed to the expansion and almost exclusive emphasis on medical technology. It does little to prevent people from getting ill, even though it may be of benefit to them once they do. Too much of our resources are going to treating illnesses and not enough to preventing them. Thus, while there are pro- and anti-medical technology forces, each is looking at the situation from its own perspective. It really comes down to a philosophy of medicine. Do we put most of our emphasis on prevention and public health, or on diagnosis and treatment and medical care? Thus far, the medical care forces have won the battle hands down.

Yet, the "anti" forces are not idle. Labor spokesmen, civic organizations and numerous minority groups who feel they are being squeezed out of the medical care system have been putting pressure on their congressional representatives and leaders to take measures to halt the escalation of medical care costs. Congress has responded in two directions, passing legislation to reduce medical costs and to plan a more rational system.

With respect to cost containment measures, Congress has made efforts to reduce the cost of care by encouraging the use of physician and dental assistants. While they have provided more care, especially in low income communities, it is not certain whether medical care costs have been lowered by their addition. President Nixon gave a significant boost to using lower cost ambulatory care facilities by pressing for the expansion of the nascent prepaid health maintenance organization movement with planning and construction dollars. After a number of slow starts, there has been a recent upsurge in the development of HMOs around the country. Yet, it is doubted that they will make a significant impact in weaning patients away from their relationships with private physicians. In addition, Congress has been trying to hold the line on expenditures for medical education, NIH medical technology research dollars, hospital construction funds and Medicaid and Medicare fees. While there is a renewed interest in national health insurance, the prevailing mood in Congress and the executive branch is to hold off such a far reaching and potentially costly measure until the costs of health care have been brought under control. Finally, regulatory measures as certificate of need for hospital construction and renovation, prospective rate setting which in effect sets a ceiling on the annual costs of operating a hospital, and medical audits and reviews of utilization of hospital, long term care and ambulatory services are further efforts by Congress to brake the rising costs of medical care. However, in spite of the passage of all these measures in the last five to ten years, there has been no appreciable slowing in the increased costs of such care.

This has finally led Congress to try a new tact. If health plans can actually be developed for each service region in the United States, HEW might be in a position to assess what the real problems in the system are and what alternatives might be attempted to provide improved care at lower cost. At the same time, HEW has thought that linking planning to regulation might have an impact on rising costs that neither by itself is able to accomplish.

### Health Planning and Regulation: PL 93-641

The Health Planning and Resources Development Act of 1974 was passed by Congress for the express purposes of:

1. Containing the cost of medical care and
2. Improving the quality of care

Both of these goals are laudable. However, they are potentially in conflict. How is it possible to raise the quality of care without it costing more money? Congressional leaders working in tandem with HEW officials identified ten priorities in the Act, if carried out to their maximum, would achieve both goals. Section 1502 of the Act identifies these ten priorities. Their major thrust is on improving efficiency in the use of medical services. They call for such changes as:

1. Integrating services where possible
2. Regionalizing services so that continuity of care is maintained
3. Using lower cost services such as physician assistants
4. Reducing the unnecessary lengths of hospital stay by utilization review
5. Emphasizing lower cost services such as HMOs, home health and ambulatory surgi-centers

Through these combined measures and others like them, the goal would be to wring the waste out of the medical care system. With the savings accrued from these sources, the health system agencies would be able in their plans to identify priorities for providing better services to underserved populations. Thus, out of money saved through reduction in waste and duplication of services the potential conflict between the goals of cost containment and quality would be merged into a positive accommodation. That is the theory. What is the reality as it has been played out up to this point?

**Planning:** The HSAs are required by law to develop five and one year implementation plans within two years of their creation as planning agencies. By and large almost all the HSAs have developed such plans. They are huge documents ranging from 300 pages to well over 1,000 pages in length, not including even larger appendices that have accompanied most of the plans in Region II, which includes New York and New Jersey. As a professor interested in planning, I have examined these plans and found that they more or less conform to guidelines set forth by HEW. While it is not possible to speak about region-wide priorities, one of the main components to which the goals speak are the regionalization of one or more specialized medical services. These include services requiring high costs of equipment, space and personnel such as burn centers, CAT Scanners, automated laboratory equipment, diagnostic radiology, renal dialysis and open heart surgery.

All of these services will cost more than the $150,000 minimum set by HEW guidelines, requiring review by HSAs and state regulatory bodies to determine whether they are needed. That is a commendable function of the HSAs and the state. However, in the past, the regulatory function of the HSAs (determining whether an expensive piece of medical equipment is needed) has often been in conflict with their planning function. With the development of plans, their goals should speak to the priority or importance of the region's acquiring such equipment, how many units are necessary, where they ought to be located, and for whose benefit they are used. Unfortunately, there has been an inconsistency between the state guidelines for these specialized medical technologies and the criteria used by the HSAs within the states; the HSAs themselves have developed widely differing criteria and standards for the review of such projects. One researcher has counted 32 state agencies and/or HSAs that have developed guidelines and criteria used in their review of CAT Scanners. On only four of the ten criteria identified (requirement of full-time neurosurgeon, neurologist, and radiologist and regionalization of the scanners to insure both availability and access) was there anything approaching consensus on whether to approve the CAT Scanner proposal or not.[7] If there is this degree of difference over the proper criteria to review CAT Scanners (which have received so much attention in the past three years), there is likely to be even more confusion about how to review the other specialized medical technologies.

To put rationality into HSAs' thinking, HEW developed its minimum guidelines for eleven components of health care, nine of which deal with specialized medical technology.[8] For example, no CAT Scanner should be approved unless it can show evidence of producing a minimum of 2500 scans a year. Radiation therapy for cancer cases requires approval for those proposals where at least 7,500 treatments per year will be rendered and where there is a likelihood that 450 new cancer cases will be found. 200 procedures are the minimum number required before approval can be given for an open heart surgical unit. These represent a beginning, but they still offer much room for the HSAs and state agencies to develop further criteria to determine need.

Thus, while there is some confusion about how to link the planning and regulatory functions, increasing attention is being given to medical technology because of the prominent role it plays in the costs of providing hospital services.

**Rate Setting:** In addition to planning and regulation, the Act calls for developing rate setting experiments in seven states. The purpose of the experiments is to apply different models for determining the funds required by a hospital for the following year and holding it to that level of expenditure. This is called prospective rate setting. By setting such a ceiling, the burden is then shifted to the medical facility to find ways to make its own institution more efficient rather than having this task imposed by the state. The concern about prospective reimbursement is that an institution with unusual expenses (for example, the rapid rise of gas and oil and food) over which it has little control may allow the quality of its care to suffer in order to live within its budget. On the other hand, alternatives open to an institution may be its use of less expensive medical procedures to hold down costs.

**Access:** The Act also calls for greater accessibility to services by either high risk groups such as alcohol and drug abusers, pregnant women over 35 or in their teens, or special groups with traditionally low access to service such as blacks, the elderly, the poor Spanish-speaking and rural populations. To assist these groups, a number of the HSA plans call for such changes as building clinics in these areas, using ombudspersons to reach out to them, and providing lower cost physician assistants. Regardless of the mechanism used, greater costs will result. The hope is that savings accrued by the closing of the thousands of acute care beds not needed in the region will be used to pay for these services.

### Initial Outcomes of Federal Response to Rising Costs

While it is too early to clearly state that these moves have not worked, early studies raise questions about their ultimate success in curbing costs. Most of the attention has been given to the certificate of need program. First promulgated by a few pioneering states, it became a national program when built into the health planning act as a required function of HSAs and state health planning agencies. A look at the record thus far indicates that over 90% of all proposals reviewed by the HSAs and SAs are approved.[9] Furthermore, another study clearly shows that while there has been a slowdown in acute care hospital bed growth, there has been no decrease in hospital capital expenditures. This is because the hospitals have shifted their money to purchasing more expensive medical technology.[10] Neither of these trends augur well for the future except that the studies were made before any of the HSA health plans were completed. But as noted previously, none of these plans are specific enough to give explicit guidance on what to do with proposals for specialized medical equipment and facilities. The hope is that once such standards are designed and added to the federal minimum guidelines, that there will be an overall decrease in capital expenditures.

With respect to prospective reimbursement, a recent evaluation of the seven experiments indicates that they have slowed the rate of increase in hospital costs. However, the amount of savings is small compared to the overall cost increases in the health field.[11] In short, it may not make a major contribution in holding down costs.

Regionalization of expensive medical technology has been attempted by some HSAs. Where there already exists an over-supply of such services, it will be difficult to force a hospital or other medical facility to give up an under-utilized service. The strong reaction by the hospitals with vastly under-utilized pediatric and obstetric beds to integrating them with other hospitals has met with a chorus of resistance from hospital officials, physicians and their patients who have been accustomed to using those facilities. One can expect similar resistance to HSA plans to reduce the under-utilized, costly medical technology of a region. On the other hand, where an under-supply exists, the HSAs and SAs are in a position to make better decisions with respect to the use of new proposed services. However, even if regionalization of medical technology is a success, it will have two potentially negative consequences. First, it will foster the monopoly of these services by medical schools and their teaching hospital affiliates. This may well lead to an emphasis on their use for teaching and research purposes rather than for diagnosis and treatment of illnesses of the general population. It will consequently lead to greater inaccessibility for certain populations in the region which traditionally have had difficulty being admitted to these prestige hospitals: the poor, the minority patient and the elderly. Second, it will also lead to increasing the costs of a hospital stay in one of these hospitals. This is understandable in a hospital where the most expensive medical equipment, medical staff, and most difficult-to-treat patients are concentrated. As a corollary of this, however, it may lead to the continued deemphasis of physicians practicing in community hospitals. Patients, in turn, will prefer to be treated at the best medical school and teaching hospitals rather than the community hospital even though the local institution is more appropriate for their less complicated illnesses.

But, most important of all, the new medical technology has not shown that its use has had any appreciable impact in improving the overall health status of the population. The studies previously noted clearly show that for that small portion of the population treated with the latest medical innovations, there has been a saving of life. However, the same study shows that there has been a significant increase in most of the diseases being treated by these medical technologies. It's almost like saying that given a vast sum of money I can save ten lives, but at the same time another twenty persons show up with the same illnesses who cannot be saved. In short, the high cost of medical technology can never win the game if the bottom line requires both a reduction in mortality and morbidity rates. Almost all the medical technologies are used to treat people *after* they become ill. What is being done to help people stay well so they will not require such treatment?

### What Can We Do?

There are three strategies which collectively can make an impact on the reduction of health costs while increasing the health status of the population. These are a medical strategy, a self-help strategy and a community-based strategy.

1. *Medical strategy:* There is waste and duplication in our medical system. People do become ill and need medical attention. A small portion of these need to be treated by one of the expensive medical procedures. However, this requires the continued training of bio-medically oriented physicians. There has to be a re-orientation in medical education such that biomedical training of physicians is not considered the most important educational orientation, but only one of several strands, including family medicine and community medicine. It may be that the medical educators are so wedded to their model of education that they cannot break out of the mold. If that should indeed prove to be the case, then a national health service or a variant of the model proposed by the Consumer Commission may well be needed to overcome the rigidity of medical education.

Secondly, the expensive medical technology must be rationed and placed where it can best serve the needs of people, research and physician education. Recently developed HSA plans appear to be on the right track in their efforts to regionalize these medical technologies. Whether they are best placed only in medical schools and teaching hospitals or spread among various hospitals which can become the centers for different specialties has to be discussed and resolved in each region according to its pattern of medical care. In this way, duplication of services will be avoided and the quality of care will be improved because of the full utilization of the available high technology equipment. While the costs may be higher in those institutions with medical specialties, the costs for care in the region will generally be lower. Since the great majority of patients can be treated in community hospitals, it would seem an overall saving of costs will occur in the region.

Although it represents only a start, the medical guidelines developed by HEW are a good place to start in the implementation of the regionalization concept.

1. *Bed-Population Ratio for General Hospitals:* Less than four short-term hospital beds per 1000 persons with corrections made for age, seasonal population fluctuations, urban areas, rural areas, and areas with referral hospitals.
2. *Occupancy Rate for General Hospitals:* An average 80% occupancy rate for general, short-term hospitals with corrections for seasonal fluctuations and rural areas.
3. *Obstetrical Services:* 2000 deliveries annually in

an obstetrical unit located in an SMSA of 100,000 or more people. Average annual occupancy rate of 75% with some exceptions for distance.

4. *Pediatric In-Patient Services: Number of Beds:* A minimum of 20 beds in a pediatric unit with some exceptions for distance. The occupancy may vary between 65% for small units (20-39 beds) and 80% for large units (80 or more beds).
5. *Neonatal Intensive Care Units:* Neonatal problem births per 1000 should not exceed four and the unit should have at least 20 beds.
6. *Open Heart Surgery:* 200 procedures annually, except no new units opened until those existing units perform at least 350 procedures.
7. *Cardiac Catheterization Unit Services:* 300 procedures in an adult unit and 150 in a pediatric unit on an annual basis, except no new units opened in a hospital without an open heart surgery unit or until an existing unit performs 500 procedures annually.
8. *Radiation Therapy:* A unit to serve a population of 150,000 persons and have at least 450 new cancer cases per year, except no new unit to be started until existing one(s) perform at least 7,500 treatments per year.
9. *Computed Tomographic Scanners:* A unit should perform 2,500 procedures per year except no new unit until existing units perform 4,000 procedures annually.
10. *End-Stage Renal Dialysis:* Should conform to standards and procedures in DHEW regulations governing conditions for coverage of suppliers of ESRD services (20 CFR Part 405, Subpart U).

2. *Self-Help Strategy:* In recent years, the mass communication media have spent considerable time discussing the dangers and symptoms of the three major causes of mortality in this country: heart disease, hypertension, and various forms of cancer. While some may question the nature of the scare tactics used in these health messages, the message has necessarily been received by millions of people. People are becoming more conscious about the suddenness with which their family members, friends and relatives can die. People, noting the often poor attention the deceased had given to maintaining their own health prior to their deaths, may very well have been spurred into examining how they care for their own health and welfare. Whatever the reason, people are more conscious of their health habits and well-being and in increasing numbers are doing something about it. Whereas the life expectancy among white males has increased only about three years between 1900 and 1960, a recent study detailed seven simple exercises, if carried out routinely, would on an average increase a 45-year-old's longevity by about 11 years.[12] Because these seven basic health habits are so simple that anyone can do them without medical guidance, they are worth repeating:

1. Eat three meals a day.
2. Eat breakfast every day.
3. Engage in moderate exercise two or three times a week such as taking long walks, bicycle riding, swimming, jogging or gardening.
4. Sleep seven to eight hours nightly.
5. Refrain from smoking.
6. Limit alcohol consumption to one or two drinks at most a day.
7. Maintain a moderate weight for your age, height and bone structure.

Of course, those with special addictions or health problems which make it difficult to carry out these seven practices will need special counseling and/or treatment. As one researcher has noted, "increase in life expectancy . . . has been the result primarily of reductions in death rates of early age, not in the lengthening of the "normal" life span."[13] Implementing these seven health habits speaks exactly to that issue. A 45-year-old man following 0-3 of these health habits has a life expectancy of 21.6 years whereas a person who practices 6-7 of them will have a life expectancy of 33.1 years.[14] None of these seven rules has anything to do with medical technology or high cost of medical care. It is simply a matter of a person caring enough about his or her own well-being.

3. *Community Strategy:* A person is not an isolate. Persons live in communities, travel to work, spend a considerable portion of their lives at a work, home, or education site and are affected by what happens to them (either subtly or very manifestly) in these places. The noise of horns blowing, machines whirring, the odors of pollutants from chemical plants and waste dumps, the sour taste of heavily treated water are the more manifest effects on people. More subtly, people are affected by radiation, food preservatives of certain types, dangerous and untreated contaminants in the water, and the routinized tensions of home, work and educational facilities. While these subtle and manifest elements profoundly influence our physical and mental well-being they can only be dealt with on a community-wide basis. One individual cannot tell a factory owner to stop polluting the air and the water; tell a mass transit official that the subways are too noisy; or tell a teacher or principal that he/she receives too much homework and is served poor quality food in the cafeteria. Collective actions are required to deal with such community-wide problems. While none of the actions has anything to do with medical technology, failure to improve these community problems can only lead to physical

and/or mental breakdown requiring medical treatment.

While no one knows how much it will cost to implement the many changes required in the environment, in our work-places, and in ourselves, one can anticipate that such changes will be costly. However, unlike the emphasis on medical technology and treatment procedures which add little to the overall well-being and health status of the population, the three types of strategies recommended above should bring about a higher benefit-cost ratio and improved health status outcomes than have been produced so far by strictly medical interventions. In short, there is much more that all of us can do for ourselves and which we have in many instances already started to do than in the past. We are becoming more the masters of our well-being than the persons of authority—including professors, physicians and political leaders—are willing to give us credit for.

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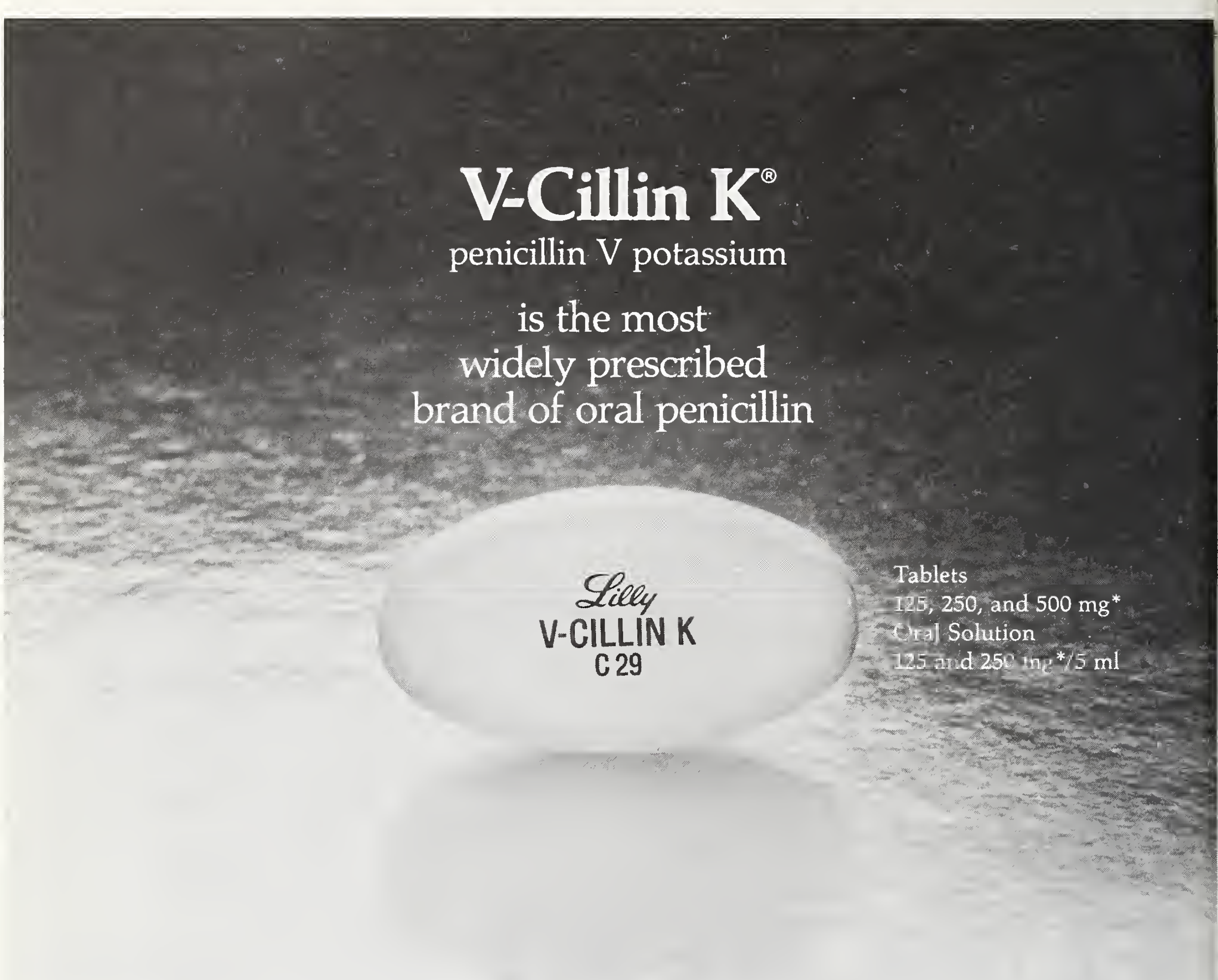

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**Warnings:** Serious, occasionally fatal, anaphylactoid reactions have been reported. Some patients with penicillin hypersensitivity have had severe reactions to a cephalosporin; inquire about penicillin, cephalosporin, or other allergies before treatment. If an allergic reaction occurs, discontinue the drug and treat with the usual agents (e.g., epinephrine or other pressor amines, antihistamines, or corticosteroids).

**Precautions:** Use with caution in individuals with histories of significant allergies and/or asthma. Do not rely on oral administration in patients with severe illness, nausea, vomiting, gastric dilatation, cardiospasm, or intestinal hypermotility. Occasional patients will not absorb therapeutic amounts given orally. In streptococcal infections, treat until the organism is eliminated (minimum of ten days). With prolonged use, nonsusceptible organisms, including fungi, may overgrow; treat superinfection appropriately.

**Adverse Reactions:** Hypersensitivity, including fatal anaphylaxis. Nausea, vomiting, epigastric distress, diarrhea, and black, hairy tongue. Skin eruptions, urticaria, reactions resembling serum sickness (including chills, edema, arthralgia, prostration), laryngeal edema, fever, and eosinophilia. Infrequent hemolytic anemia, leukopenia, thrombocytopenia, neuropathy, and nephropathy, usually with high doses of parenteral penicillin. [102175]

***Equivalent to penicillin V.**

*Additional information available to the profession on request.*

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900416

# The Medical Device Amendments of 1976—Panacea or Pox?

### (Second of Two Parts)

JAMES F. COARSE, M.S.

## Introduction

The passage of the Medical Device Amendments of 1976 (P.L. 94-295), an amendment to the Federal Food, Drug and Cosmetic Act, culminated a decade of efforts to provide safe and effective medical devices for human use. The salient aspects of this new federal legislation, as well as the responsibilities of the F.D.A. with respect to medical devices were discussed in Part 1 of this manuscript. The potential effects of this landmark legislation on users of medical devices will be discussed in Part 2.

## Part II—The Medical Device Act and its Effect on Users

Manufacturers and users of medical devices have generally recognized the need for medical device standardization and regulation. Although the legislation does not regulate the hospital or its environment, the law directly or indirectly creates responsibilities, liabilities and limitations in addition to the positive elements of the act. Despite the American Hospital Association's support of medical device legislation, its cautious optimism has been tempered with warnings that innovation must not be stifled; that impact on hospital costs must not be forgotten; that in any phasing plan, the investments in current inventory must not be ignored; and that hospitals be included in any notification-system warning of potentially defective devices.[23]

Generally, benefits to users of medical devices resulting from the new law are clear. The regulatory control requires manufacturers to be more exact in the design and manufacture of products. By establishing various industry standards and performance requirements, the act provides users with some assurance of safety and effectiveness. This is the primary intent of the legislation. The FDA has been provided with sweeping authority to regulate devices and quickly remove unsafe and ineffective equipment from the marketplace. Under the general controls of the act all devices must conform to standards regarding uniform labeling, device identification and classification, and adequate directions for use. Under these statutes, health care professionals and users will receive from FDA and manufacturers much more information on the use, maintenance, installation and hazards of devices. With such information hospitals will be able to apply more quality engineering procedures to reduce equipment costs and provide better patient care. Conversely, the hospitals legal and moral responsibilities will increase beyond the general law of negligence with increased access to information. Another significant benefit of medical device legislation will be increased communications between users and manufacturers during development of government standards. The increased communication could provide an effective basis for more precise purchase and manufacturer specifications for devices.

It is also clear that several potentially negative aspects resulting from the new law may affect users. The potential adverse effects of the act focus on increased costs of devices to the health care community and delayed availability of new products. Higher costs that manufacturers incur in complying with the regulations pertaining to device legislation will ultimately be passed on to consumers (hospitals, patients, etc.). Because of intense competition in the medical device industry and lack of final regulations, the extent of such cost increases at this time remains unclear.

Although several alternatives to premarket testing are provided in the act, legislation will nevertheless delay availability of devices, and in some cases may even prevent it. Some authors have suggested that the lag between technological development and application resulting from any degree of regulation will

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JAMES F. COARSE, M.S., Assistant Director of Pharmacy Services, University of Connecticut Health Center, John Dempsey Hospital, Farmington.

interfere with the quality of patient care. Generally regulatory controls can be viewed as a process by which innovation is slowed enough to allow a deliberate examination of product change from the viewpoint of safety and effectiveness. Experience with drugs such as thalidomide and practolol further emphasize and reinforce the prudence of this concept. The onus is on the FDA, the health care community, consumers and the industry to ensure that availability of beneficial products is not unduly impeded under such a process.

The health care community must also be aware of specific limitations imposed by the medical device law. Physicians may find it more difficult to obtain custom devices because of increased responsibilities and liabilities that industry must assume for producing such devices. It appears that custom devices will be available only on a limited basis at higher costs. Investigational devices are now subject to FDA application, approval and informed consent requirements. Therefore, institutional review committees are now required judge and process protocols in the same manner as investigational drugs protocols, thus assuming more legal and moral responsibilities to assure appropriate levels of safety and effectiveness in the investigative process. The act also provides limited provisions which permit the physician to dispense with the patients' informed consent if the physician states in writing that obtaining informed consent is not medically feasible.

Another serious point for consideration involves the physician's and hospital's responsibility in complying with FDA hazard notification or defective device announcements. Under new statutes, institutions share responsibility with the manufacturer for informing users (in-house) and patients of defects, of nonconformance, and of any action that should be taken to eliminate risks involved with the use of the device. Hospitals could conceivably become involved with recalling the device, replacing the device and correcting defects. Moreover, they can be liable if there is an accident and no action has been taken. There may also be serious moral and ethical considerations involved if the physician or institution disagrees with an FDA order requiring the individual patient to be informed. Thus, hospitals will need to develop efficient recall systems to ensure that incoming notices are properly identified and routed to the responsible individuals. Additionally, follow-up procedures need to be established to ensure that prompt and effective action is taken.

Under S 519 of the act, hospitals may assume the responsibility of informing FDA when a device has a defect or deviates from established standards. A hospital may be subject to criminal penalty if it knowingly fails to inform FDA of a defect.

Another section of the recall procedure requires manufacturers to repair, replace or refund the purchase price of defective products. The financial burden on health care professionals and institutions may be relieved only when the user can demonstrate the device was properly used and maintained. Not only is there increased burden on the manufacturer, but there is increased attention focused on the user in connection with problems with devices. The hospital will have an increased burden of providing effective equipment control, maintenance and educational programs to ensure proper application and operation of equipment. One aspect of this section remains unclear. In the case of implantable devices, it is not known if the manufacturer will have to incur hospital and surgical costs associated with repair, replacement or refund of purchase price of devices.

Although the new medical device legislation does not actually regulate hospitals or other health care institutions, the standards create responsibilities and liabilities beyond the general law of negligence in the malpractice arena for the health care community. The new Environmental Standards—Functional Safety and Sanitation Standards of the Joint Commission on Accreditation of Hospitals[24] have already increased requirements for the systematic and periodic verification of performance and use specifications. These increased responsibilities will increasingly require adequate pre-purchase evaluation, preventative maintenance, repair and inservice training programs to be established in institutions. Such programs will require in-house biomedical equipment technicians and possibly a clinical engineer or the services of an outside service organization or possibly a shared service organization if one is available.

Although adding these services will undoubtedly increase operational costs, the implications of legislation, the increasing sophistication of equipment, and the lack of knowledgeability of users warrant such increases. Properly tailored and managed programs can provide the proper mechanisms to satisfy the responsibilities of medical device legislation and the new J.C.A.H. requirements impose.

## Conclusion

The Medical Device Amendments have been the focus of much debate for the past ten years. The phenomenal scientific progress and tremendous contributions of the medical device industry in recent years raises an instinctive fear of the stifling effect on innovation, potential spiraling costs and delayed availability of potentially life-saving devices. Fortunately, the act is neither a criticism nor an indictment of the scientific community or of the free enterprise system. The law was not passed impulsively out of anger at a ruthless industry. The new legislation is an honest and time-tempered desire to serve the public interest. The law deals with a sensitive interface where the newest product of the inventive mind is applied to the most difficult and resistive forms of human suffering.[25]

It is impossible at this time to objectively and accurately evaluate the overall benefits of implementing this legislation. It may require another decade to determine whether the benefits of legislation will have outweighed its negative effects. Hopefully, government, industry and the health-care community will unite in such a task at the appropriate time.

One fact is certain, medical device amendments are not a panacea. The legislation will ensure only a minimum level of safety and efficacy. It is the responsibility of the entire health care community, industry and the government to continue to communicate, contribute, question, debate, compromise and ultimately agree on various aspects of formulation of regulations and revisions in the law if necessary. It is incumbent on all concerned parties to provide the proper leadership and expertise; assign the proper priorities, and expend the necessary effort to make P.L. 94-295 the exception to the rule.

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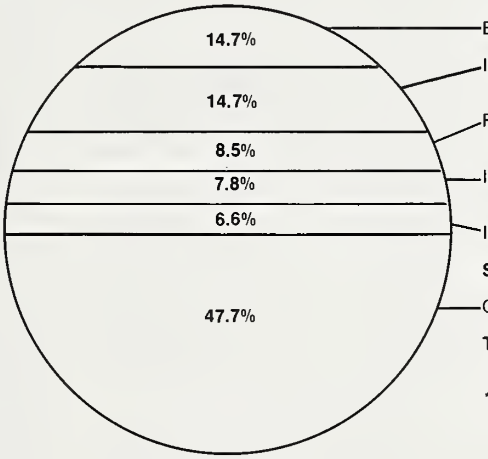
# Summary of Malpractice Claims Against Psychiatrists by Allegation

**258 Claims (October 1, 1973—December 31, 1978)**

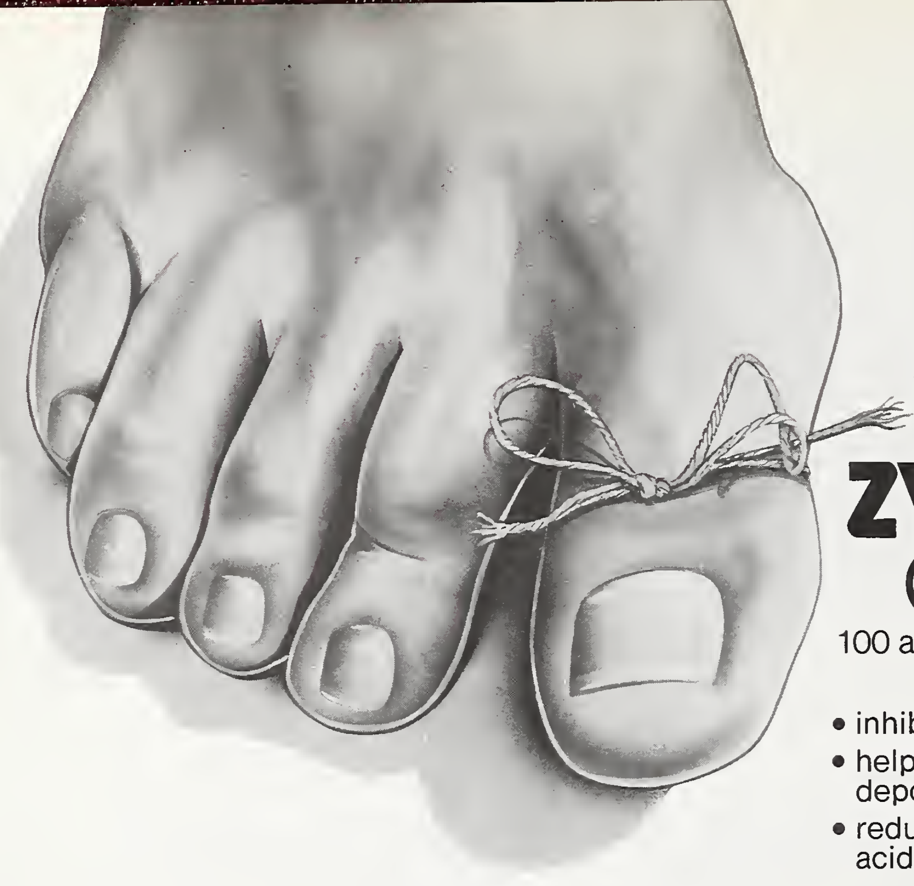
This graph shows the most frequent malpractice claim allegations against psychiatrists insured by St. Paul Fire and Marine Insurance Company. It is based on data from a claims analysis systems report compiled by The St. Paul since October, 1973. As illustrated in the graph, allegations of emotional trauma and improper treatment account for the greatest percentage of malpractice claims against psychiatrists.



| *ALLEGATION | NUMBER OF CLAIMS |
|---|---|
| EMOTIONAL TRAUMA | 38 |
| IMPROPER TREATMENT *LACK OF SUPERVISORY CONTROL* | 38 |
| FAILURE TO DIAGNOSE *MENTAL PROBLEMS* | 22 |
| IMPROPER TREATMENT *DRUG SIDE EFFECT* | 20 |
| INFORMED CONSENT | 17 |
| **SUBTOTAL** | 135 |
| OTHER | 123 |
| **TOTAL** | 258 |

**Five leading allegations = 52.3% of base.*

**An article** in a recent issue of *Medical World News* reported that of 81 malpractice suits against psychiatrists which have been reviewed by the American Psychiatric Association's insurance committee, 54 were defensible and 25 were not. The most common patient complaints for these suits include drug reactions, improper treatment or supervision, or involve sex relations or suicide.—*Malpractice Digest,* March-April, 1979.



A reminder

**ZYLOPRIM**

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- inhibits uric acid formation
- helps prevent urate crystal depositions in synovia
- reduces risk of uric acid lithiasis

**INDICATIONS AND USE: This is not an innocuous drug and strict attention should be given to the indications for its use. Pending further investigation, its use in other hyperuricemic states is not indicated at this time.**

Zyloprim® (allopurinol) is intended for:

1. treatment of gout, either primary, or secondary to the hyperuricemia associated with blood dyscrasias and their therapy;
2. treatment of primary or secondary uric acid nephropathy, with or without accompanying symptoms of gout;
3. treatment of patients with recurrent uric acid stone formation;
4. prophylactic treatment to prevent tissue urate deposition, renal calculi, or uric acid nephropathy in patients with leukemias, lymphomas and malignancies who are receiving cancer chemotherapy with its resultant elevating effect on serum uric acid levels.

**CONTRAINDICATIONS:** Use in children with the exception of those with hyperuricemia secondary to malignancy. The drug should not be employed in nursing mothers.

**Patients who have developed a severe reaction to Zyloprim should not be restarted on the drug.**

**WARNINGS:** ZYLOPRIM SHOULD BE DISCONTINUED AT THE FIRST APPEARANCE OF SKIN RASH OR ANY SIGN OF ADVERSE REACTION. In some instances a skin rash may be followed by more severe hypersensitivity reactions such as exfoliative, urticarial and purpuric lesions as well as Stevens-Johnson syndrome (erythema multiforme) and very rarely a generalized vasculitis which may lead to irreversible hepatotoxicity and death.

A few cases of reversible clinical hepatotoxicity have been noted and in some patients asymptomatic rises in serum alkaline phosphatase or serum transaminase have been observed. Accordingly, periodic liver function tests should be performed during the early stages of therapy, particularly in patients with pre-existing liver disease.

Patients should be alerted to the need for due precautions when engaging in activities where alertness is mandatory.

Nevertheless, iron salts should not be given simultaneously with Zyloprim. This drug should not be administered to immediate relatives of patients with idiopathic hemochromatosis.

**In patients receiving Purinethol® (mercaptopurine) or Imuran® (azathioprine), the concomitant administration of 300-600 mg of Zyloprim per day will require a reduction in dose to approximately one-third to one-fourth of the usual dose of mercaptopurine or azathioprine. Subsequent adjustment of doses of Purinethol or Imuran should be made on the basis of therapeutic response and any toxic effects.**

*Usage in Pregnancy and Women of Childbearing Age:* Zyloprim® (allopurinol) should be used in pregnant women or women of childbearing age only if the potential benefits to the patient are weighed against the possible risk to the fetus.

**PRECAUTIONS:** Some investigators have reported an increase in acute attacks of gout during the early stages of allopurinol administration, even when normal or subnormal serum uric acid levels have been attained.

It has been reported that allopurinol prolongs the half-life of the anticoagulant, dicumarol. This interaction should be kept in mind when allopurinol is given to patients already on anticoagulant therapy, and the coagulation time should be reassessed.

A fluid intake sufficient to yield a daily urinary output of at least 2 liters and the maintenance of a neutral or, preferably, slightly alkaline urine are desirable to (1) avoid the theoretic possibility of formation of xanthine calculi under the influence of Zyloprim therapy and (2) help prevent renal precipitation of urates in patients receiving concomitant uricosuric agents.

Patients with impaired renal function require less drug and should be carefully observed during the early stages of Zyloprim administration and the drug withdrawn if increased abnormalities in renal function appear.

In patients with severely impaired renal function, or decreased urate clearance, the half-life of oxipurinol in the plasma is greatly prolonged. Therefore, a dose of 100 mg per day or 300 mg twice a week, or perhaps less, may be sufficient to maintain adequate xanthine oxidase inhibition to reduce serum urate levels. Such patients should be treated with the lowest effective dose, in order to minimize side effects.

Mild reticulocytosis has appeared in some patients.

As with all new agents, periodic determination of liver and kidney function and complete blood counts should be performed especially during the first few months of therapy.

**ADVERSE REACTIONS:**

*Dermatologic:* Because in some instances skin rash has been followed by severe hypersensitivity reactions, it is recommended that therapy be discontinued at the first sign of rash or other adverse reaction (see WARNINGS). Skin rash, usually maculopapular, is the adverse reaction most commonly reported.
Exfoliative, urticarial and purpuric lesions, Stevens-Johnson syndrome (erythema multiforme) and toxic epidermal necrolysis have also been reported.
A few cases of alopecia with and without accompanying dermatitis have been reported.
In some patients with a rash, restarting Zyloprim (allopurinol) therapy at lower doses has been accomplished without untoward incident.

*Gastrointestinal:* Nausea, vomiting, diarrhea, and intermittent abdominal pain have been reported.

*Vascular:* There have been rare instances of a generalized hypersensitivity vasculitis or necrotizing angiitis which have led to irreversible hepatotoxicity and death.

*Hematopoietic:* Agranulocytosis, anemia, aplastic anemia, bone marrow depression, leukopenia, pancytopenia and thrombocytopenia have been reported in patients, most of whom received concomitant drugs with potential for causing these reactions. Zyloprim® (allopurinol) has been neither implicated nor excluded as a cause of these reactions.

*Neurologic:* There have been a few reports of peripheral neuritis occurring while patients were taking Zyloprim. Drowsiness has also been reported in a few patients.

*Ophthalmic:* There have been a few reports of cataracts found in patients receiving Zyloprim. It is not known if the cataracts predated the Zyloprim therapy. "Toxic" cataracts were reported in one patient who also received an anti-inflammatory agent; again, the time of onset is unknown. In a group of patients followed by Gutman and Yü for up to five years on Zyloprim therapy, no evidence of ophthalmologic effect attributable to Zyloprim was reported.

*Drug Idiosyncrasy:* Symptoms suggestive of drug idiosyncrasy have been reported in a few patients. This was characterized by fever, chills, leukopenia or leukocytosis, eosinophilia, arthralgias, skin rash, pruritus, nausea and vomiting.

**OVERDOSAGE:** Massive overdosing, or acute poisoning, by Zyloprim has not been reported.

**HOW SUPPLIED:** 100 mg (white) scored tablets, bottles of 100 and 1000; 300 mg (peach) scored tablets, bottles of 30, 100 and 500. Unit dose packs for each strength also available.

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# Continuing Self-Education of Medical Editors and Writers

### EDITH SCHWAGER

Complacency loses ball games. It also breeds carelessness and indolence in areas far removed from the palestra.

It is regrettable to see some medical editors and writers slacken their pace as they ease into the comfortable middle of their careers. Perhaps they are too easily satisfied with the results of their work. They consider that they have spent the better part of their adult lives interviewing, researching, consulting, drafting papers, and editing pseudoscientific, illiterate articles. Unlike grey-eyed Athena, these workers did not spring full-armed from the brow of Zeus. Much painful (although perhaps gratifying) effort went into education and training in the beginning years. Now, they sigh, they can take it a little easy, not work quite so hard.

But success, even the endogenous kind, is not a spur. The charm of the familiar may eventually prove fatal to intellectual growth.

Exactitude is at once the beacon and the hallmark of the good medical editor/writer. Painstakingness must be a faithful companion. An intelligent, enthusiastic, inquiring editor, though inexperienced, may actually be a better editor than a complaisant, complacent, experienced one.

The more seasoned editors and writers should be using their mentation to the utmost. Instead, many of them lean back, savoring their ability to make—at last—a decent living; perhaps they can even congratulate themselves on sending at least two of the children to college. The temptation to drift downstream, to deal only with the ordinary stresses, one day at a time, must be almost irresistible.

But wise editors and writers will not heed the siren song of Circe. They will go to the bookcase and open that interesting book on usage. They will revel in word play and the images that our opulent language can evoke. "The IRS dealt the *coup de grâce* to the new firm." (Perhaps this arm of the government should have used a misericord.) They will read magazines and newspapers as if they had just had the good fortune to learn English.

They will write that tactful letter to the editor of the local newspaper explaining that *kudos* is already singular, and so there is no such word, in either English or Greek, as "kudo." They will point out—gently—to a feature writer that the proper spelling of the phrase is "corpus delicti," not "corpus delecti." (There is something macabre and vaguely Freudian about the incorrect version.)

#### Odd Things to Wonder About

If you have encountered a dictionary of initialisms, abbreviations and acronyms, you may have discovered the correct meaning of those arcane expressions MEDLARS, MEDLINE, MeSH and ISBN. If not, please read on. MEDLARS, the registered initialism for *Med*ical *L*iterature *A*nalysis and *R*etrieval *S*ystem, is the "computerized" medical literature retrieval services of the National Library of Medicine, publisher of an old friend, *Index Medicus*. (According to the *American Heritage Dictionary*, but not *Webster's Third New International Dictionary*, there really is such a word as "computerized.") MEDLINE is MEDLARS "on-line." MeSH stands for *me*dical *s*ubject *h*eadings used by NLM in indexing and cataloging materials. ISBN is the abbreviation found in almost every book on the copyright page. The *I*nternational *S*tandard *B*ook *N*umber contains digits, in accordance with an arbitrary international numbering system, representing the group (that is, language or country), the publisher, and the individual book number.

I have often wondered how many physicians or statisticians—or medical writers/editors in general—know that the "Student" of the well-known $t$-test is a pseudonym. Recently I was delighted to come across the story in my serendipitous reading of a book on elementary statistics.*

William S. Gosset (1876-1937), a statistician who worked for the Guinness brewery in Dublin, empirically derived a statistical quantity having to do with large-sample experiments. Because Guinness forbade the publication of research by its employees, Gosset sent his findings to Karl Pearson (1857-1936), at one time his teacher. Beginning in 1908, Gosset's research results were published under the pseudonym "Student" in the journal *Biometrika*, of which Pearson was, fortunately, the editor. Karl Pearson is generally considered the father of the modern science of statistics. Professor E.S. Pearson, a world-famous statistician also, is the son of Karl.

Many writers and editors are shocked to learn that there is no such word as "miniscule." The correct word, *minuscule*, is derived not from "mini"-anything

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EDITH SCHWAGER is employed by Dorland & Sweeney, Inc., Philadelphia, Pennsylvania, as editor. She is the editor of *Medical Communications*, the official journal of the American Medical Writers Association.

***Elementary Applied Statistics*, by Marvin Lentner, Ph.D., Tarrytown-on-Hudson, Bogden & Quigley, 1972, page 139 (ISBN 0-8005-0022-9).

but rather from the Latin *minus*, which means exactly the same in English as it does in Latin, that is, *less*. The Latin for "smallest" is *minimus*. The word *miniatura* means (1) a picture on a small scale, or (2) the art of manuscript illumination, and comes from *miniare* (to illuminate a manuscript; to color with cinnabar or red lead). So *miniature* is not mini-anything either.

Writers or editors who have occasion to use *corpus luteum* know that the plural is *corpora lutea*. But some of these careful writers and editors may fall prey to the current barbarism of using *data* as a singular noun; they can give innumerable reasons for using a singular verb with it. These reasons fall on my deaf ears, because there is a perfectly good and useful singular form—*datum*. At least, no one has yet had the temerity to engage in logodaedaly by coining "datas." Not so far. I fear I shall open the newspaper some day and find that someone has minted this spurious word.

In the same vein (an unfortunate phrase in some contexts) is *media*, a word almost always used nowadays—erroneously—as a singular. *Media* is the plural of *medium*, like *datum* a perfectly good and useful singular form. One may speak of the electronic or printed media; a medium is print (newspapers, magazines, books); another medium (electronic) is television; still another is radio. Taken together, they *are* media.

A common confuser is *precipitous*. It is *precipitate* that means sudden. If a mnemonic association is needed, one has only to recall the *s* in *precipitous* (*s*teep) and the *a* in *precipitate* (*a*brupt).

An investigator may be principled but not principle. In this context, the proper spelling is *principal*, as in "principal investigator." The mnemonic could be "the school princi*pal* should be a *pal*," or, as Theodore Bernstein suggests, one might relate the *al* to *al*mighty or *al*l-important. The noun *principle* can be related to ten*e*t.

Judgments are handed *down*, but indictments are always handed *up* (sometimes literally).

*Fortuitous* means "happening by chance," not "fortunate." If some day you need a fancy synonym for *fortuitous*, you might try *aleatoric*, a word sometimes applied to music such as John Cage's, as well as other endeavors; it stems from the Latin *aleator*, gambler or dice player, from *alea*, a dice game.

The prefix *nor*, as in norepinephrine (noradrenaline) and other chemical substances is derived from the German phrase *Nitrogen ohne Radikal* (nitrogen without radical).

This particular item is hardly world-shaking, but I find it fascinating. In the 1930s Dr. Charles F. Richter, of the California Institute of Technology, devised a scale, theoretically open-ended, to measure the strength of earthquakes. The interesting part is that each point in the scale stands for a magnitude ten times greater than the preceding number. A number 9 earthquake, therefore, would be 100,000,000 times as strong as a quake of the magnitude of 1. So far no earthquake has been recorded with a Richter number of 9. It has been calculated that the famous San Francisco earthquake in 1906 would have registered 8.3 on the Richter scale.

Tutankhamun buffs might like to know that the representation of the sacred asp, a sign of sovereignty seen on the headdresses of ancient Egyptian rulers, is a uraeus.

As a general rule, "multifactorial" is a word properly used only by geneticists or mathematicians; if a situation comprehends many variables, perhaps "multifactoral" (this word is not found in dictionaries) could be coined to meet this need.

## All Writing Is Creative

Writers and editors—whether medical or otherwise—cannot afford to stand still. The English language *does* change. Usage *does* change. What was permissible yesterday may today be, at the best, old hat and, at the worst, substandard. And what is now substandard may, unfortunately, become the usage of tomorrow. *Major, fantastic, viable, enormity, livid, hopefully*—all good words when used correctly but not faddishly used incorrectly—may come into the language in their inaccurate meanings.

All good contributions to the beauty and richness of the English language should be gratefully accepted.

Attentiveness at seminars and workshops on medical writing and editing will repay the expenditure of time, money and effort many times over, in many ways. Association with other good editors and writers is a most rewarding way of staying in the mainstream.

Editors and writers can keep *au courant* by reading literary magazines and supplements regularly. Certainly the classics should be reread often.

Thus a great measure of fulfillment can be achieved by practitioners of those potentially ennobling professions—editing and writing.

Expository and science or medical writing should not be so different from "creative writing." All writing is creative.

The products of our work will outlast us, with any luck at all, by at least a couple of centuries. That is both a chilling and an exhilarating thought. But the chill lasts only a moment for those who write and edit their best. The exhilaration lasts forever.

# The President's Page

## Can Health Care Planning Be Dangerous to Your Health?

Shortly after the passage of Public Law 93-641 (The Health Planning Act), I was privileged to attend a meeting in Boston at which the head of the planning division of HEW outlined for us some of the expectations which would result from the passage of this bill.

It was interesting to note the accuracy with which he was able to predict some of the regulations that would become effective one year later since at that time the Health Planning Act was being touted as a prime example of how local community input would bear heavily on national planning objectives. Even more amazing was the fact that some of the conclusions being stated were based on data which the chief of health planning at that time admitted might not be available, and as a result might have to be "winged."

This might not be relevant except that several years later we are still faced with no centralized system of data-gathering in the State of Connecticut. A major effort toward this goal was made by the Connecticut State Medical Society but it failed because of lack of support by the agencies that would ultimately need its data.

How vitally important accurate data is to all of us can be illustrated by two recent events:

1. A current survey revealed that one of our most affluent communities would qualify as a medically under-served area because only one physician's office existed within its geographic borders. Interesting to note, however, was that no one had evaluated the area for the total number of physicians who resided within its geographic bounds. Nor was it apparent from the study that the area was served by over thirty physicians whose offices were within one or two miles of the geographic borders involved and that the affluent residents had rather unlimited mobility. How this area could qualify for a government grant whose purpose it is to provide increased physician availability defies credibility.

2. Another area designated as statistically under-served relied on population data that was outdated. The study failed to take into account the number of buildings that had been burned to the ground, the number of stores that had been boarded up and closed and the number of apartments that were empty. In addition, an adjacent area was practically abandoned as evidenced by "For Sale" signs hanging on half empty buildings.

Health planning must play a significant role in establishing priorities for the spending of tax payers' monies, however, it must be done effectively and efficiently without wasting that money. It must not be in conformity with preconceived notions nor to satisfy private vested interests. Above all, it must be held accountable for its results.

Recently in trying to increase the number of primary care physicians in certain communities, some State Legislatures have attempted to correct shortcomings by legislative fiat. Most of this type of legislation is designed so that state universities must give priority to state resident applicants to the State Medical School before consideration can be given to an applicant from outside the confines of that State. Had this been the situation in Connecticut, we would have suffered over the years since the overwhelming number of physicians now practicing in our State were trained in medical schools outside of this State. If Connecticut were so foolish as to emphasize geography and quotas rather than qualified applicants there could be a dearth of excellent physicians practicing here. By limiting ourselves that way we would be denying our citizenry of doctors who after studying here would decide to stay and practice in our State. How myopic!

If these kinds of attitudes begin to hold sway then we will, indeed, be appropriately labeling some health planning *dangerous to the public health.*

Edward A. Kamens, M.D.
*President*

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# Reflections from the Dean's Office

## Simple Causes, Simpler Answers

ROBERT U. MASSEY, M.D.

*Essentia non sunt multiplicanda praeter necessitatem.* William of Occam.

I believe that I first heard of Occam's Razor when I was a medical student. My professor of medicine, listening to my struggling to define a clinical problem, reminded me not to forget Occam's Razor. He explained, because he sensed that I had not understood, that it was generally unprofitable to multiply causes, and that one was more likely to be right in trying to attribute most findings to a single diagnosis. Not always, however; one could get hung up on the razor.

The notion of cause is not as self-evident as it seems. Aristotle divided causes into four classes: material, formal, efficient, and final. In medicine, we are mostly concerned with the efficient cause, which Aristotle defined as "that by which a change is begun or stopped."

I remember being told by a professor of pediatrics that reactivation of tuberculosis was the result of (caused by?) a negative nitrogen balance and a negative calcium balance. Rheumatic fever, he said, was mild or severe, depending upon the patient's nitrogen balance. He certainly did not mean that diet was the whole story, but he had in mind the idea of some material cause. He clearly was thinking of the economic reasons for inadequate protein and calcium intake, and of the relationship between poverty and some diseases.

Arguments to show that medicine, especially scientific medicine, is ineffectual in coping with disease, or even in explaining it, are now stylish. The decline in tuberculosis deaths which seemed to follow a slope unaffected by the introduction of streptomycin in 1946 and isoniazid in 1952, is used as an especially telling debating point. The remarkable decrease of tuberculosis in isolated groups since the use of specific chemotherapy tends to go unrecognized. In the Navajo tribe tuberculosis morbidity and mortality did not decline sharply until after 1952. It is unlikely that the diet of black and Puerto Rican children is much richer in protein than that of poor Irish and Italian children a generation ago, and yet rheumatic fever is a rare disease in most of North America in 1979.

It had always seemed to me that the tubercle bacillus and the Group A hemolytic streptococcus represented the causes, the efficient causes, of these two diseases, and that they, like smallpox, could be eradicated from the face of the earth. Something like this also seemed true for diphtheria, meningitis, pneumococcal pneumonia, poliomyelitis, typhoid, syphilis, malaria, and many other diseases. We could either cure the disease by specific agents which attacked the microorganisms, or we could prevent the disease by stimulating immunity. There seemed to be no theoretical limit to our ability to prevent infectious diseases by immunization, and to cure those we had missed by using some chemotherapeutic or antibiotic agent.

In another sense, however, we know very little about causes. How *Mycobacterium tuberculosis* causes in some the disease which we recognize as tuberculosis while others remain well is not known, nor can we explain why other mycobacteria are relatively harmless. We are only beginning to imagine what happens between a mycobacterium and its host to begin the development of a tubercle or to cause a fever. Somewhere in the cascading reactions there is an initial event, the activation of some enzyme, the beginning of an immunologic response, and this looks as though it might be knowable. This is the kind of knowledge which we need to have if we are to cure or prevent those disorders where the immune response has gone wrong, such as systemic lupus or rheumatoid arthritis, or where the immune surveillance may have been drowsing, such as in cancer or relapsing tuberculosis.

Undoubtedly social disorder and tension, polluted air, tobacco smoke, and too much or too little food are material causes of disease and general human misery. But we do not know the efficient causes of hypertension, atherosclerotic heart disease, lupus, or carcinoma of the lung. When we do, we shall prevent them or cure them, and probably do it quite simply. This is what Lewis Thomas has called the high technology of medicine. The social problems and the problems of human misbehavior will be harder to solve, and they are not the problems for which medicine is best suited. Problems, like causes, should not be multiplied endlessly if we ever hope to have the time to find useful answers.

---

ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

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# Commission on Hospitals and Health Care: Five Years of Litigation

## Part II

JOHN Q. TILSON, ESQ.

Last month's report on litigation involving the Commission on Hospitals and Health Care dealt with Commission control of hospital rates and budgets. Such litigation has been only a part of the total picture. There has also been substantial litigation with respect to the Commission's authority in connection with so-called certificates of need. The number of appeals in this area has been much less to date than in the budget field; there have been some fifty budget and rate appeals and only half a dozen certificate of need appeals. It is likely, however, that litigation in connection with hospital capital projects will increase in the future. The Commission's record in court has been essentially as unsuccessful as in the budget area.

Three of the certificate of need cases which have been litigated to date involve CT scanners. In the first case the Commission tried to prevent a group of Stamford doctors from acquiring a CT scanner. Former Justice MacDonald, sitting as a state referee, held that the Commission statute does not apply to capital expenditures by private physicians.[1] A second CT scanner case involved Stamford Hospital, whose application for a scanner had been rejected. The court once again found against the Commission. Judge Kulawicz ruled that the scanner had been denied on the basis of Commission guidelines which had not been properly adopted as regulations and that furthermore Stamford Hospital had been denied equal protection under the law in that scanners had been awarded by the Commission to applicants with obviously less qualifications than those possessed by Stamford Hospital.

A third CT scanner case involving the Hospital of St. Raphael is awaiting decision in the Superior Court. The Commission had denied the hospital's application for a scanner because two scanners were already in use in the City of New Haven at Yale-New Haven Hospital and a third scanner was being operated by a group of private physicians in the community. The Commission held that since the privately owned scanner was not being used to full capacity, the hospital had no need for such a piece of equipment. The case involves many of the same issues which were considered in the Stamford Hospital case, including improper use of regulations and lack of "equal protection."

Temple Street Associates, which is the group of private physicians involved in the St. Raphael CT scanner case, has also been a party to two court decisions involving its right to operate an ambulatory surgery center.[2] In these companion cases the Commission had denied Temple Street Associates' application to operate an ambulatory surgery center and directed the two hospitals in the City of New Haven to prepare plans for operating such a service. The court held that the conditions under which the application was denied were improper and authorized the appellant to proceed with its plans for the surgicenter.

In a recent case involving, for the first time, two Connecticut hospitals in opposition to each other, Meriden-Wallingford Hospital received CHHC authority to expend approximately $150,000 in connection with plans for a new hospital. World War II Veterans' Memorial Hospital, also in Meriden, took an appeal which the court dismissed on the ground that the hospital was not "aggrieved." Memorial Hospital has taken a further appeal to the Connecticut Supreme Court.

One further major piece of litigation is still pending in the courts. This involves an appeal by Yale-New Haven Hospital from the Commission's decision early in 1979 to cut by fifty-three beds the application of Yale-New Haven to construct a new hospital to replace the obsolete New Haven Unit. The hospital has alleged numerous procedural irregularities in the Commission decision-making process and an arbitrary disregard by the Commission of the bed needs of the institution. The court's decision in this case will obviously go a long way in determining the impact the Commission will have on health care in Connecticut.

JOHN Q. TILSON, ESQ., Legal Counsel to the Connecticut Hospital Association; partner of Wiggin & Dana, New Haven.

*This article was prepared at the request of the Connecticut Hospital Association.*

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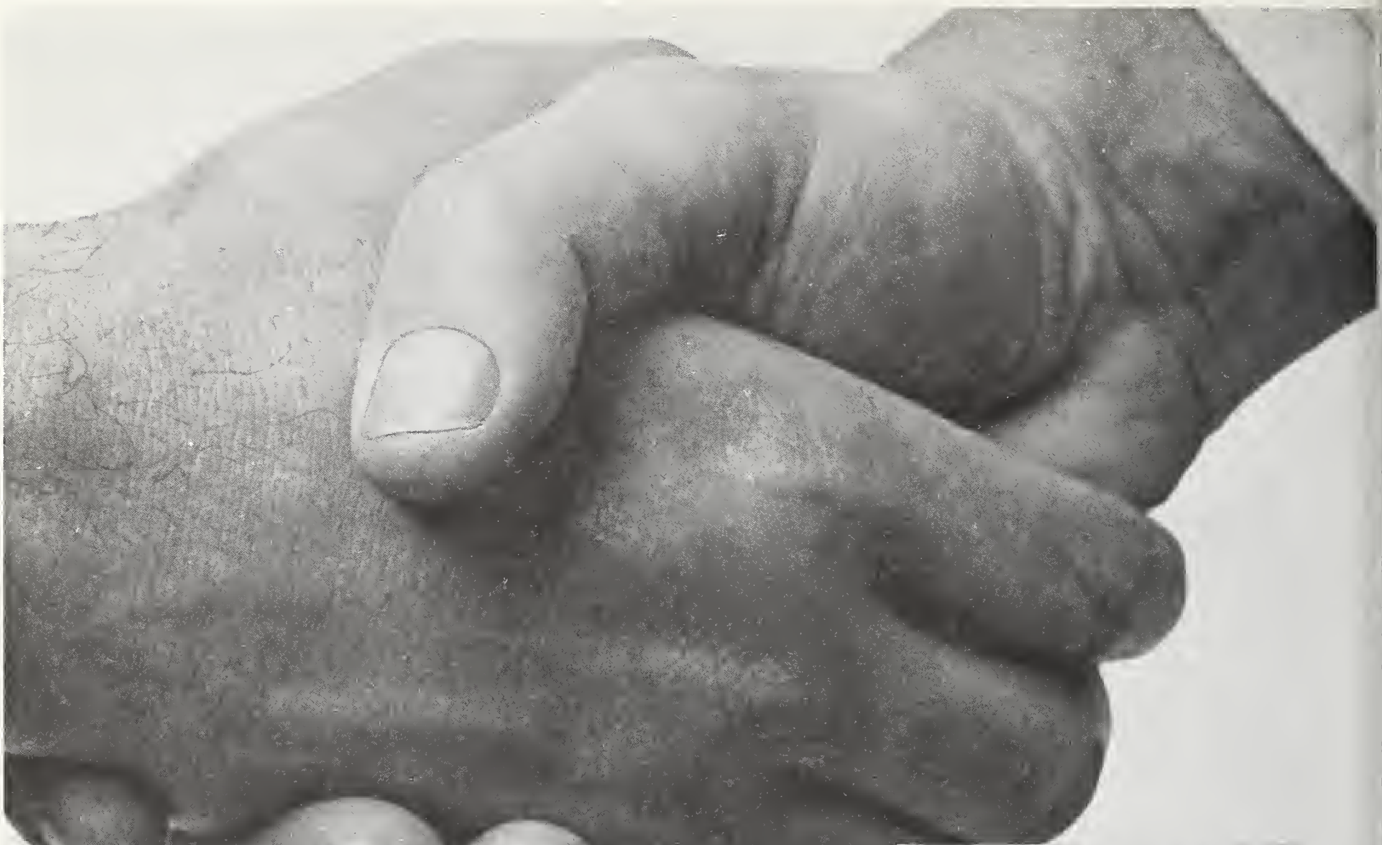

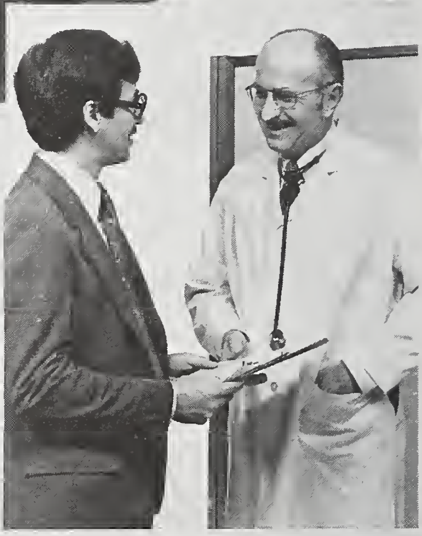

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# After *Quinlan:* The Impact of the *Saikewicz* Decision

JOSEPH M. HEALEY, J.D.

The decision of the New Jersey Supreme Court in the case of Karen Quinlan[1] represented the first step in the development of acceptable policies to govern medical decisions affecting the incompetent patient with no reasonable likelihood of returning to normal functioning. In summary, the Court allowed Joseph Quinlan, father of the patient, to serve as her guardian and to exercise her rights, including the right to refuse treatment. The decision of Mr. Quinlan, when accepted by his daughter's physician, would be reviewed by a hospital-based "prognosis" committee, whose sole responsibility was to determine the likelihood of the patient's return to cognitive, sapient life. Upon an appropriate finding, the committee would approve the decision not to treat and all parties would be immune from civil or criminal liability. It would not be necessary for the parties to petition the court in each individual situation as subsequent cases arose.

If the *Quinlan* case represents a first step, then the case of Joseph Saikewicz[2] represents the second step. Joseph Saikewicz was a 68-year-old resident of Belchertown State School. He was profoundly retarded, described as having an I.Q. of 10 and a mental age of 2-2/3 years. He had been physically strong, well-built, nutritionally nourished, ambulatory, but unable to communicate verbally. He had been hospitalized since 1923 and had been at Belchertown since 1928. On April 19, 1976, he was diagnosed as having acute, myeloblastic, monocytic leukemia. It was necessary for a decision to be made about initiating chemotherapy. The superintendent of the institution petitioned the local probate court for the appointment of a guardian and for guidance in deciding whether to begin treatment of the patient. Subsequently, a guardian was appointed; a hearing was held. The judge, at the recommendation of the guardian, refused to order treatment. On appeal, the decision was sustained, though a written opinion did not appear until after the death of Mr. Saikewicz.

It is hard to do justice to this complicated case in a few paragraphs. The opinion is not a model of clarity. It has been a source of confusion and frustration within the medical profession, within the legal profession and between the medical and legal professions. Nonetheless it is a critically important case and offers some contrast to the *Quinlan* case.

The Massachusetts Court in *Saikewicz* addressed three fundamental issues: (A) the nature of the right of any person to decline potentially life-prolonging treatment; (B) the legal standards that control the decision to employ life-prolonging (not life-saving) treatment for an incompetent patient; and (C) the procedures to be followed in making such decisions. In essence, the Court held that both competent and incompetent persons have the right to decline potentially life-prolonging treatment.

Such rights, though not absolute, are important rights which must be protected. In identifying the mechanism for protecting these rights, the Massachusetts Court rejected the *Quinlan* approach (a prognosis committee). It stated its conviction that the courts must not shift their responsibility to a committee or panel. In an often-quoted section of the opinion, the Court wrote:

> "We do not view the judicial resolution of this most difficult and awesome question—whether potentially life-prolonging treatment should be withheld from a person incapable of making his own decision—as constituting a 'gratuitous encroachment' on the domain of medical expertise. Rather, such questions of life and death seem to us to require the process of detached but passionate investigation and decision that forms the ideal on which the judicial branch of government was created. Achieving this ideal is our responsibility and that of the lower court, and is not to be entrusted to any other group purporting to represent the 'morality and conscience of our society,' no matter how highly motivated or impressively constituted."[3]

Though disagreement exists among commentators about which cases need court review and why, a fundamental difference exists between the two courts and their two solutions.

Connecticut has not yet had a case or statute to deal with these issues. It is important that we study the New Jersey and Massachusetts cases carefully, so we might profit from their experiences.

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JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington.

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# EDITORIALS

## Trends in the Anatomic Distribution of Colorectal Cancer

Several recent reports suggest that the distribution of carcinomas of the colorectum is changing.[1, 2, 3, 4] These statistics raise important questions concerning the screening methods to be used for a disease that claims 50,000 lives annually in the United States.

The Hartford Hospital Tumor Registry records were examined retrospectively over 3 year spans during each decade, from the 1935-1937 interval to the 1975-1977 interval. All tumors documented by pathologic study were included. There was a persistent increase in the incidence of colorectal cancer during each succeeding decade, averaging 61 patients annually (1930's), 106 patients annually (1940's), 122 patients annually (1950's), 142 patients annually (1960's), and 190 patients annually (1970's). At the same time, there was an increase in the average incidence of cancers of the cecum and ascending colon, from 11.4% (1930's) to 22.5% (1970's). Simultaneously, rectal cancers diminished in average incidence from 42.7% to 33.2% (See Figure 1). The average incidence of cancers in the transverse colon, including the hepatic and splenic flexures (10.8 - 15%); the descending colon (3.9 - 6.2%); and the sigmoid colon (25 - 30.3%) fluctuated with only minor variations during the past 40 years.

### Comments

In a large series of cases seen between 1937-1948, 54% of colorectal tumors were situated in the rectum, 17% in the sigmoid, and 14% in the right colon (including the hepatic flexure).[5] A rather pronounced decrease in incidence of rectal cancers and an increased incidence of right-sided cancers was first noted by Cady et al in 1974.[1] In Connecticut, the incidence of ascending colon and sigmoid carcinoma has increased from 1940-1973, especially in patients more than 65 years of age.[4] In other parts of the United States, similar spatial trends have been seen.[2, 3]

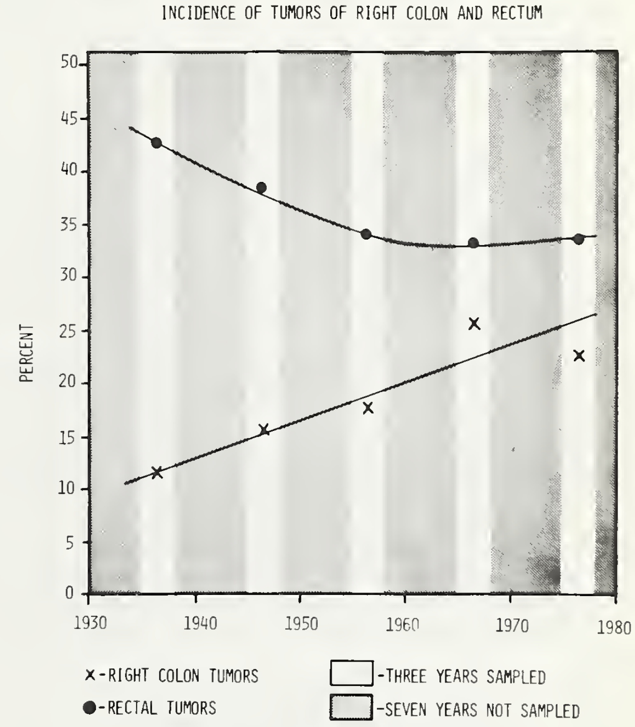

Figure 1
Distribution Patterns of Adenocarcinomas of the Ascending Colon and Rectum, Hartford Hospital.

Changes in distribution of colorectal cancer reflect in part enhanced detection of more proximal tumors using colonoscopy and air contrast barium studies together with effective removal of polyps in the rectum and lower sigmoid colon. As epidemiological studies of dietary and activity patterns and urbanization are being done, the former teaching that up to half of all colorectal cancers are within the reach of the examining finger and two-thirds within the reach of the rigid sigmoidoscope[5] should be discarded. In screening programs of patients more than 40 years of age, Hemoccult testing of the stool is a valuable screening technique that is reproducible, easily performed, and of low expense.[6] The flexible fiberoptic sigmoidoscope may replace the rigid proctoscope in evaluating "high-risk" patients with a history of adenomatous polyps or individuals with Hemoccult positive stools. Seventy to eighty percent of polyps and tumors lie distal to the mid descending colon in the range of the flexible sigmoidoscope.[7] Cost-effective screening techniques need continuing reevaluation. Implicit in developing effective screening programs is the fact that close to 1 in 4 colorectal cancers currently lie in the proximal colon.

John P. Welch, M.D.

*Assistant Professor,*
*Department of Surgery,*
*University of Connecticut Health Center, Farmington*

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## Blue Cross and Blue Shield Medical Necessity Project

The Blue Cross and Blue Shield Associations, the umbrella organizations coordinating the activities of local Blue Cross and Blue Shield Plans across the country, have recently asked all Plans to implement the latest phase of a cost and quality control program. Known as the Medical Necessity Project, it urges Plans to deny benefits for tests and procedures unless specifically ordered by a physician as necessary for a particular patient.

The program was developed in collaboration with national medical specialty organizations and has the endorsement of the American College of Physicians, the American College of Surgeons, the American College of Radiology, and the College of American Pathologists.

The project is aimed at curbing two types of occurrences. First, it has identified 42 surgical and diagnostic procedures considered to be of unproven value, redundant when performed in combination with other procedures, or unlikely to provide additional information when repeated. Another 26 diagnostic tests have been categorized as obsolete, not indicated or non-specific. It recommends that coverage be denied for these procedures unless the physician cites the medical necessity for their use. Blue Cross and Blue Shield of Connecticut has implemented a special review system for any of these procedures on our schedule of benefits so that treatment can be covered when appropriate.

Second, and more recently, the project has recommended that tests performed as part of the admission process would be excluded from coverage unless a physician specifically orders them for each medical and surgical patient. The purpose, of course, is to avoid tests that are done routinely rather than for specific medical indications.

As the initial step in implementing this phase of the Medical Necessity Project here, Blue Cross and Blue Shield of Connecticut has asked hospitals to complete a questionnaire concerning their use of and thoughts on admission batteries. Although not all the survey responses are in, the results do reveal there is a diversity of policies among Connecticut's general hospitals and that automatic testing of patients is more common than generally may be believed. In addition, the responses indicate that the tests included in these admission batteries vary from institution to institution, as do the levels at which policy decisions are made. Naturally, as a follow-up to this survey, we will want to meet with medical and administrative staffs to discuss our findings and methods of implementing the Medical Necessity Project in Connecticut.

However, I do want to assure you that we recognize some hospitals have established sound procedures for routine tests; some have documented the effectiveness of limited routine batteries; others have modified standing orders for routine diagnoses; still others have policies under review. Let me say we will back the use of existing programs that meet cost and quality standards.

Let me also assure you that it is not the intent of the project to deny benefits for necessary services nor to transfer the financial obligation for necessary services to the patient. Rather, we want to limit pointless tests which increase the cost of care for everyone without increasing its quality.

I hope these remarks have given you an understanding of the Medical Necessity Project and that you will support it. Should you have any questions about it, please do not hesitate to contact us.

Joseph F. Duplinsky

*President*
*Blue Cross & Blue Shield of Connecticut, Inc.*

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## COUNCIL MEETING

Thursday, June 7, 1979

### Attendance

Present were: Drs. Kamens, James, Canzonetti, Backhus, Mendillo, Ragland, Sadowski, Freedman, Van Syckle, Fabro, Whalen, Cramer, Rubinow, Anderson, Magram, Parrella, Barrett, Zlotsky, Jameson, Beck, Abbot, Shenker, Eslami, Tierney, Bobruff and Sonnen.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Sweeney, Mr. Brunell and Mr. Tomat (FCMA).

Absent were: Drs. Hess, Friedberg, McGarry, Seide and John J. Barrett.

### Organizational Meeting

The organizational meeting of the Council for 1979-80 was called to order by the President, Edward A. Kamens. Following some opening remarks and the introduction of Council members, elections of a Chairman and a Vice-Chairman of the Council for 1979-80 were held. Those elected: Chairman—Andrew J. Canzonetti, Waterbury; Vice-Chairman—Guy W. Van Syckle, Danbury.

### Approval of Minutes

Note was made that the published minutes of the meeting of March 28, 1979, had been approved at the House of Delegates meeting on May 2, 1979, as part of the "Report of the Council."

### Reports from Physicians Serving on State and Federal Agencies

It was reported that funding problems of PSROs have resulted in a general cutback in administrative services. Three out of the four PSROs executive directors have resigned their positions or are in the process of leaving their organizations Merrill B. Rubinow, Manchester, the new appointee to the Connecticut Commission on Hospitals and Health Care, reported that nursing homes were the subject of the Commission's most recent meeting and mentioned that health maintenance organizations (HMO) are being represented as the panacea for rising health care costs.

### Report of the President

President Kamens reported on his activities since the Annual Meeting and on some of the communications he has received. He mentioned that James E.C. Walker, M.D., had expressed an interest in undertaking a jail care study in Connecticut as a possible project for the Connecticut State Medical Society.

It was VOTED to encourage James E.C. Walker, M.D., to pursue a jail health care study in Connecticut and report back to the Council at its August meeting on any specific proposal.

The President apprised the Council of a request received from Harvey Wachsman, M.D.J.D. relative to a proposal for a CSMS operated malpractice insurance company

It was VOTED to have Dr. Wachsman present in writing his proposal for a new malpractice insurance company to the CSMS' Committee on Professional Liability.

Dr. Kamens was contacted by Larry Pickett, M.D., Chairman of the Medical Examining Board, concerning problems of the disabled physician and the need for assuring due process in all cases.

It was VOTED that President Kamens and James O'Brien, M.D. (Chairmen of the CSMS' Committee on Drug Abuse) meet with Dr. Pickett in order to secure more information for the Council on the subject of disabled physician legislation and to check into the feasibility of improving the present statutes if appropriate.

The President mentioned that he had been in receipt of a letter from Robert R. Henderson, M.D., of the Metropolitan Life Insurance Company requesting CSMS participation in Metropolitan's Second Opinion Program.

It was VOTED to have the President and Mr. Norbeck meet with Dr. Henderson to secure more information on Metropolitan's Second Opinion Program and specific details as to what would be expected of the CSMS.

### Report from Subcommittee on Administrative Organization and Planning

After discussion, it was VOTED not to adopt the subcommittee's report pertaining to specific tenure for CSMS elected officials.

### Appointment of Council Subcommittees and Ad Hoc Committees 1979-80

The Council reviewed the roster of its subcommittees and ad hoc committees for 1978-79 and made necessary deletions and appointments for 1979-80 as follows:

1. *Fiscal Subcommittee:* Deleted the names of Hilliard Spitz, Trudeau Horrax and Charles M. Krinsky—all of whom are no longer members of the Council. Appointed—Frank Abbot, Jerome Freedman to the Subcommittee.
2. *Subcommittee to Study and Revise Bylaws:* Deleted the name of Irving Rosenthal and added T. Peter Jameson.
3. *Subcommittee on Administrative Organization and Planning:* Deleted the names of Robert Harkins and Charles Krinsky and added Todd Anderson and Jerome Bobruff.
4. *Subcommittee on Publications:* Deleted the name of Charles Krinsky and added Frederick Barrett.
5. *Ad Hoc Committee on Hospital Costs:* VOTED to disband the subject ad hoc committee.
6. *Ad Hoc Committee on Medical Technology:* VOTED to postpone action as to continuance of this committee.

### Committee for a Better Assignment Rate

It was VOTED to accept Dr. Irving I. Rosenthal's resignation with thanks from the Committee for a Better Assignment Rate and to empower the President to appoint his successor. Isadore H. Friedberg, Newington, has been appointed to fill this position.

### Advisory Committee to the Medicaid Fraud Control Unit

After discussion of a resolution submitted by Dr. Polivy relative to a request for assistance from the Medicaid Fraud Control Unit, it was VOTED to approve the resolution with minor amendments:

BE IT RESOLVED: That the Council, based on an action of the American Medical Association and the Connecticut State Medical Society against fraud, approves of assisting the State of Connecticut, Division of Criminal Justice, and urges utilization of the following basic document for a Title XIX Advisory Panel providing medical expertise to the Department of Criminal Justice and the Department of Income Maintenance.

1. The President and Dr. Polivy, taking into account the need for county and specialty representation, select a group of nominees for submission to the Assistant State's Attorney and the Commissioner of the Department of Income Maintenance.
2. All physicians would serve voluntarily without remuneration.
3. The Committee may utilize county review committees in their deliberations, where they are in operation.
4. This Committee shall in its considerations of a case assure that the physician involved has not been deprived of Due Process.
5. The Committee shall be advisory only to the Medicaid Fraud Control Unit as an interpreter of the panel's expertise on decisions and recommendations.
6. The Committee would also be available to the Department of Income Maintenance in its investigations and audits prior to referral of a case to the Medicaid Fraud Control Unit of the Justice Department. Information is to be obtained as to liability of the committee.

### CSMS Semi-Annual Meeting

It was VOTED to hold the 1979 CSMS Semi-Annual Meeting in the Bridgeport area. Proposed date—November 14 or 15, depending on availability of facilities.

### Report of National Council of State Committees on Continuing Medical Education Meeting

It was agreed that the Connecticut delegation to the AMA would submit a resolution to the 1979 AMA Annual Convention (July) inquiring about CME accreditation of intrastate institutions by state medical societies, an action which had been urged by the AMA House of Delegates at the 1978 Interim Meeting (Dec.).

It was VOTED to pursue the formation of a medical advisory committee by Commissioner Maher.

It was VOTED to request the CSMS Committee on Legislation to undertake legislative efforts to undo the statutory determined relationship between private office visits and institutional out-patient reimbursements.

It was VOTED that the CSMS Liaison Committee to the Department of Income Maintenance pursue the idea of having the Department allow the billing of more than one service on a single welfare form.

It was VOTED to have the CSMS Committee on

Legislation investigate the possibility of joint legislative activity with the Department of Income Maintenance where common interests prevail.

### Appointment—Chairman of Committee to Study Perinatal Morbidity and Mortality

It was VOTED to approve the appointment of Dr. Robert A. Herzlinger, Bridgeport, as Chairman of the Committee to Study Perinatal Morbidity and Mortality.

### Life Members

It was VOTED to accept for information the following list of Life Members:

William G. Ames, Essex (M)—1/1/79
John C. Haley, Hamden (NH)—1/1/79
Paul H. Lavietes, New Haven (NH)—1/1/79
James F. Ferguson, Wallingford (NH)—1/1/79
William E. Furniss, Bristol (H)—1/1/79
William S. Norton, New Haven (NH)—1/1/79

### Miscellaneous Business

*Connecticut Medicine:* On the recommendation of the Editor of *Connecticut Medicine,* it was VOTED to send a congratulatory note to Boehinger Ingelheim Ltd. for its new Research and Development Center in the Danbury area. The organization has provided advertising support in *Connecticut Medicine.*

*Guidelines—Home Oxygen Therapy:* After discussing a report presented by the Chairman of the CSMS Committee on Peer Review Systems, the Council VOTED to approve with commendation its contents with regard to review guidelines for Medicare B coverage of chronic home oxygen therapy for pulmonary disease patients.

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on June 7, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

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## NOTICE TO CONTRIBUTORS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS.** This material may be obtained from the *Journal* office, Tel.: (203) 865-0587. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to:

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# ANNUAL REPORTS

## OF THE CONNECTICUT STATE MEDICAL SOCIETY

1978 - 1979

### Report of the Council

**Andrew J. Canzonetti, M.D.,** ***Chairman***

The Council has met four times since the semi-annual session of the House of Delegates last November. Detailed minutes of the December, January, February and March meetings have been received previously by all members of the House. This report, therefore, is limited to a summary of the major matters considered by the Council and the actions taken thereon. At the conclusion of the report, as appendices, there are published a series of items of business which are transmitted by the Council to the House for consideration and action. The number given to each of the appendices is identical with the number of the related sections of this report.

**1. Federal Trade Commission**

Late last November, a decision was received from an administrative law judge with the Federal Trade Commission that the American Medical Association, the Connecticut State Medical Society and the New Haven County Medical Association should stop prohibiting physicians from advertising their services. This decision was rendered despite the claim of the AMA, CSMS and the NHCMA that these organizations do not restrict physicians from advertising, as long as the information is factual and not misleading or fraudulent and does not resemble solicitation. The Chairman of the AMA Board of Trustees stated that this is "the most shocking and pervasive attack on professionalism" as in the ruling is a provision that the AMA will be permitted to participate in the setting of ethical guidelines for doctors "advertising only after first obtaining FTC approval." The claim that the FTC has no jurisdiction over non-profit organizations was also discounted by the administrative law judge who stated that the AMA, CSMS and NHCMA are associations "organized to carry on business for its own profit or that of its members," as covered by the FTC Act. The AMA president stated that the decision challenged the very tenets of a free society.

The decision of the FTC administrative law judge will be submitted to the full Board of the Federal Trade Commission for review. Following a report by the Society's legal counsel, and lengthy discussion, it was VOTED to appeal the decision through the hearing of the full Board of the FTC and then to reappraise the situation at that time. The decision from the Board could be available as early as July, 1979.

**2. Committee on Insurance**

The Society's Committee on Insurance apprised the Council of recent developments relative to the Society's sponsored insurance plans. After thorough review of the information provided by the Committee, the Council decided that in order to protect those members who already have a group overhead insurance program, the Society should continue to support the program being currently administered by the Schiff Agency and also support the sale of overhead insurance by the Ayr Agency to supplement the present coverage.

**3. Reports from Physicians Serving on State and Federal Agencies**

At every Council meeting, reports are given by physicians serving on such agencies as HSA's, SHCC, PSRO Statewide Council, etc. These reports keep the Council abreast of what is going on in these various agencies. Relative to this subject, Mr. Norbeck was requested to prepare and submit a plan for additional staffing in order to carry out the Council's desire to implement a mechanism to deal with government agencies plus any other needs which need be addressed impacting on the practice of medicine. A report was submitted by the Executive Director at the March Council meeting entitled "Future Staff Needs of CSMS" outlining proposals as to the functioning of additional staff. The Council VOTED to endorse the proposals made in the report.

**4. Department of Social Services**

Having received several letters from members relating to the problem of interpretation of procedure codes used in determining Social Services payments to physicians, it was VOTED to send a letter to the Department pointing out past and current Society cooperation and that the inflation factor and continuing viability of the program warrants consideration of revisions in the payment schedule. Special meetings have also been scheduled to review and discuss mutual problems.

**5. Connecticut Ambulatory Care Study**

It can now be said that the Connecticut Ambulatory Care Study has been completed. The newly revised Chapter 9 and the revised Critique were reviewed by an ad hoc committee, approved by the Council and transmitted to HEW.

**6. Proposed Plan for a CSMS Impaired Physician Program**

The Committee on Drug Abuse Education submitted a proposal for a CSMS Impaired Physician Program and following discussion it was VOTED to approve of the Committee's report (listed below) and request the Committee to proceed with the plan and report back to the Council on its progress.

*Proposal*

(a) Recruit a voluntary Caring Committee of concerned specialists by seeking recommendations from key individuals.

(b) Provide an inservice workshop program for this group, using talent from within and outside the state.

(c) Install a special confidential phone line at the CSMS office, with staff trained to take only what information is necessary for immediate referral to a Caring Committee physician for call back and followup. Work out system for logging calls and referrals.

(d) Announcement of program through: 1. Traveling presentation to county association annual meetings and CSMS House of Delegates; 2. Article in "Connecticut Medicine"; 3. Features in CSMS and Auxiliary newsletters, county newsletters; 4. Direct communication to hospital staff chiefs.

(e) Seek periodic reports from Caring Committee for program evaluation.

**7. Administration Organization and Planning**

At the Semi-Annual Meeting of the House of Delegates, the House VOTED to approve various policies to strengthen the structure and operation committees of the Society. These policies will go into effect as of this meeting of the House of Delegates. As of this annual meeting, no committee chairman shall serve more than 3 consecutive years and members are expected to attend all meetings and failure to attend at least 50% of the meetings or three consecutive meetings without a valid excuse will constitute resignation from the committee.

Also, members of the Council shall not serve on more than two standing Society committees as voting members. These are just some of the highlights of the report that was presented to you last November. Along these lines, the Council has under study whether there is any need to establish some length of tenure for our officers of CSMS. An organizational outline which would determine the progression through official chairs of the Society was presented to the last meeting of the Council and, following detailed discussion, was tabled for further consideration at the next meeting of the Council.

**8. Report of the Nominating Committee**

The Council, acting as the Society's Nominating Committee, has prepared and approved a slate of nominations for all offices and committee posts elected by the House. The slate is published in this Handbook under "Report of the Nominating Committee" and the Council recommends its approval. (Appendix Item No. 8)

**9. Annual Reports of Standing Committees, Representatives and Advisors**

Being advised by staff that none of the subject reports made recommendations for action by the House of Delegates, it was VOTED to transfer all annual reports to the House of Delegates and to direct the Speaker and/or Vice-Speaker "to make recommendations concerning the action required on each report."

**10. Proposed Changes in the Bylaws**

The Council proposes several Bylaw changes which relate to simplifying approval of Life and Student Memberships, reducing the size of the quorum of Council meetings, expediting and simplifying the acceptance of resignations and appointments to CSMS committees. In accordance with the Bylaws, these amendments were placed on the table at the Semi-Annual Meeting of the House of Delegates on November 16, 1978, published in Connecticut Medicine on one or more occasions prior to this meeting, and shall be taken off the table at this meeting and acted upon by the House of Delegates. The Council recommends the adoption of these Bylaw amendments. (Appendix Item No. 10)

**11. Grants for Medical Students**

From time to time, the Society receives requests from medical students for financial assistance for various undertakings which will assist them in fulfilling or enriching their medical education. The Council VOTED to set aside a fund of $1,000 to provide grants for this purpose. Each grant would not exceed $50.00 and an individual would not be eligible for more than one such grant in a fiscal year. Continuation of this program will be based on experience and will be re-evaluated at the end of one year.

**12. Conclusion**

I wish to express my sincere gratitude to the officers of the Society, to all members of the Council, and to the members of our staff for their continuing and dedicated efforts on behalf of the physicians and the people of Connecticut.

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## Committee on Continuing Medical Education

*Chairman:* Donald L. Brown, M.D.
*Number of Members:* 16
*Number of Meetings:* 4
*Average Attendance:* 14

*Summary of Activities:*

Through physician survey teams that make site visits to hospitals requesting CME accreditation or renewal of accreditation, the Committee makes recommendations to the Liaison Committee on Continuing Medical Education, the national CME accrediting authority since 1977. There are now some 37 hospitals in the state accredited, or pending accreditation. Only three Connecticut community hospitals remain unaccredited for CME. A list of accredited hospitals is available from the CSMS office.

This year, in order to comply with new LCCME guidelines concerning the co-sponsorship of CME programs, the Committee informed CME provider institutions and organizations that it would no longer act on requests for the "granting of Category I Credit" to individual CME programs. Instead, the Committee encouraged unaccredited CME providers to seek co-sponsorship from accredited institutions, or, in the case of medically oriented organizations, to seek organizational accreditation by application to the Committee. Several organizations have chosen this latter alternative, and accreditation is in progress.

At the national level, the Society has been represented at the AMA Annual CME Conference in October, as well as at the meetings of the National Council of State Committees on CME. Dr. Jerome K. Freedman, CSMS President, delivered a paper on "Voluntary CME" to the AMA Conference, and is the current Vice-Chairman of NCSCCME. In addition, Committee Chairman Donald L. Brown, M.D., now serves on the Review Committee of the national LCCME. The Committee's Report on CME in Connecticut, published in the January, 1978, issue of *Connecticut Medicine,* has received national attention, having been cited by several speakers at the national meetings.

The rush to mandated CME appears to have abated suddenly, and the CSMS decision to eschew the mandatory route, made in the teeth of an opposing trend, seems to be gaining currency as a way of minimizing commercialism,

*continued on page 465*

# Medical and Health News

**Efforts to regulate physician supply** are under way in several states and similar proposals are likely to develop in other states, the AMA warned in a memorandum to constituent associations and specialty societies. In Hawaii and Rhode Island, state health planning agencies are seeking to impose certificate-of-need licensure based on predetermined estimates of the number of physicians required. In California and New York, health planners are working to limit the number of physicians by regulating residency training.

Rationing of physician licenses, the AMA said, would reduce the availability of medical services, result in an artificial system that may not answer community needs, and deny the physician applicant equal protection under the law. Regulation of residency programs by specialty would reduce the supply of physicians without reducing the demand for their services, would lower the quality of services, would reduce the availability of services for those most in need, and would retard advances in the practice of medicine.

The AMA memo points out that proposals to manipulate the types of physicians being trained were defeated at the federal level in 1976 during consideration of the Health Professions Education Assistance Act. Attempts by states to use the National Health Planning and Resources Development Act for this purpose are outside the scope of the law, the AMA said.

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"**Physician Fee** and Cost Indicators," a booklet presenting a step-by-step method to help individual physicians manage their practices more efficiently and restrain fee increases, is available free of charge from the AMA. The booklet offers a dual system—the Physician's Fee Index and the Physician's Cost Index—for measuring the rate of a physician's fee increases against other economic gauges, such as the Consumer Price Index, and for measuring the physician's rate of increase in direct and overhead expenses. To order write P.O. Box 821, Monroe, Wis. 53566.

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**A federal court ruling** that the National Labor Relations Board was wrong in 1976 when it decided that interns and residents are students and therefore not covered by the National Labor Relations Act has been appealed by the NLRB. In 1977 the AMA testified before Congress that housestaff physicians are both employees and students. The AMA witness said, "Recognition of the need for educating the physician beyond medical school does not detract from the resident's employee status, but only acknowledges the dual role of the physician during this period."

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**WARNINGS**: If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly. *Drug Dependence*. Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of abuse should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with varying degrees of psychologic dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. *Use in Pregnancy*: Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential risks. *Use in Children*: Tenuate is not recommended for use in children under 12 years of age.

**PRECAUTIONS**: Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hypertension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of guanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.

**ADVERSE REACTIONS**: *Cardiovascular*: Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. *Central Nervous System*. Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache, rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. *Gastrointestinal*: Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic* Urticaria, rash, ecchymosis, erythema. *Endocrine* Impotence, changes in libido, gynecomastia, menstrual upset. *Hematopoietic System*: Bone marrow depression, agranulocytosis, leukopenia. *Miscellaneous*: A variety of miscellaneous adverse reactions has been reported by physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria

**DOSAGE AND ADMINISTRATION**: Tenuate (diethylpropion hydrochloride): One 25 mg. tablet three times daily, one hour before meals, and in midevening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release: One 75 mg. tablet daily, swallowed whole, in midmorning. Tenuate is not recommended for use in children under 12 years of age.

**OVERDOSAGE**: Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phentolamine (Regitine®) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

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References: 1. Citations available on request—Medical Research Department, MERRELL RESEARCH CENTER, MERRELL-NATIONAL LABORATORIES, Cincinnati, Ohio 45215 2. Hoekenga, M.T., O'Dillon, R.H., and Leyland, H.M. A Comprehensive Review of Diethylpropion Hydrochloride. International Symposium on Central Mechanisms of Anorectic Drugs, Florence, Italy, Jan. 20-21, 1977.

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*continued from page 463*

administrative expense, and the confusion of medical education and discipline. Science and coercion do not mingle productively among professionals.

At the Interim Meeting of the AMA House of Delegates in November, a hard sought goal of the NCSCCME was achieved, when AMA policy was adopted to support the concept of accreditation within states by state medical societies under LCCME or AMA guidelines. At present, state societies' authority is limited to the review and recommendation process. AMA representatives on the LCCME are now instructed to seek this authority for states.

The CME Committee is now in the process of designing a presurvey instrument for organizations requesting accreditation, and of reviewing and revising its accreditation materials and standards for institutions seeking renewal of accreditation. Survey activities continue unabated.

The responsibilities of the Committee on CME are increasing both quantitatively and qualitatively. By opting for a voluntary approach to CME, the Society has spared itself the onus of record-keeping and punitive enforcement. However, the Society has rightly accepted the responsibility of certifying the quality of CME available in our state through the accreditation process. To fulfill this historic charge authentically, the Committee will need the continuing commitment of CSMS Staff and funds, as well as the increasing commitment of our own time and that of the Directors of Medical Education who generously assist us in the accreditation process.

## Committee on Professional Liability

*Chairman:* Gioacchino Parrella, M.D.

*Number of Members:* 17
*Number of Meetings:* 4
*Average Attendance:* 12

*Claims Review Panel Meetings:* 40

*Summary of Activities:*

1979 was a turning point for the CSMS-Aetna Professional Liability Program, in that for the first time since 1972, a substantial refund was disbursed to the members of some 2.7 million dollars under the cost-plus program feature as a result of the better-than-anticipated experience for two preceding account years. At the same time, however, a premium increase of some 14.2% of total revenues was imposed for the current 1978-1979 Account Year as a result of sharply increased severity of newly arising claims as well as the effects of inflation on all outstanding claims. The refund more than offset the increase, so that net cost to members this year was reduced from 1% to 9% depending on classification, but the outlook for additional refunds in the near future appears at present unfavorable, because of worsening severity.

The reason for this is that although the increase of claims continues to moderate, those cases that do arise are apparently screened by increasingly skillful and specialized plaintiffs' attorneys for maximum dollar impact. Jury awards in seven figures have now arrived on the Connecticut scene, and such shock losses wreak havoc upon the most informed actuarial rate setting. The company's ability to deal in timely fashion with these trends is impaired by a recent worsening in the reporting lag—the time between the occurrence of an incident involving potential liability, and the time this incident is reported to the Aetna. Far too often the company hears of such problems for the first time from a court process rather than from the physician involved. Delayed reporting has a direct impact on the ultimate cost of the claim. Claims that could be settled easily at an early stage multiply fearsomely in value as months, and sometimes years go by. Physicians who report incidents with liability potential immediately to the Aetna have experienced a professional and supportive reception, and have enhanced the outcome of any subsequent claim, to their own advantage and that of the whole plan.

The Committee has requested that the Aetna consider applying surcharges and/or deductibles to the policies of known high-risk individuals, and to undertake new loss-control education programs. We will be working closely with the company in all such efforts.

### Current Professional Liability Premiums

The following professional liability rates are in effect for the 1978-1979 account year. These figures include primary coverage for $100,000/300,000 for physicians, or $250,000/500,000 for surgeons; office coverage; and $1,000,000 SCOPE umbrella coverage for all:

| *Class* | *10/1/77* | *10/1/78* | *% change* |
|---|---|---|---|
| I | $1023 | $1220 | +19.3% |
| II | 1714 | 2050 | 19.6 |
| III | 3239 | 3733 | 15.3 |
| IV | 4173 | 4817 | 15.4 |
| V | 5189 | 5989 | 15.4 |
| VI | 6203 | 7160 | 15.4 |
| VIII | 8231 | 9503 | 15.5 |

For many physicians, these increases were offset partially or entirely by this year's total elimination of the remaining 5% surcharge on partnerships and corporations, the 25% surcharge on employed physicians, the reduction from Rate Class III to II of physicians doing electroshock therapy, and the reduction from Class II to Class I of liver and kidney biopsy procedures. As a result the increase in the total premium pool was limited to 14.2%.

In addition, the $1,000,000 SCOPE excess coverage package was optionalized, a new Defendant's Reimbursement Coverage option was introduced, and a new payment plan was set in place, for monthly or quarterly payment of premiums at 0.5% per month on outstanding balance, with early payup option.

The new regulation on informed consent went into effect last year, after an earlier version opposed by CSMS had been rejected by the Legislature's Committee on Regulation Review. The new regulation provides that hospital medical staff bylaws require the responsible physician, except in emergency situations, to obtain proper informed consent prior to any procedure or treatment for which it is appropriate, and document such consent either by a form signed by the patient, or by a statement on the patient's hospital record signed by the physician. Since lack of informed consent is a common allegation in malpractice complaints, the CSMS and the Connecticut Hospital Association jointly cosponsored a well-attended seminar on informed consent in February, at which the thoughts of several defense attorneys were detailed to the audience of physicians, nurses and hospital administrators. The importance of documentation of the informed consent conversation between physician and patient cannot be overstated with respect to the successful defense of physicians.

### Committee on Peer Review Systems

*Chairman:* Sidney L. Cramer, M.D.

*Number of Members:* 21
*Number of Meetings:* 3

*Summary of Activities:*

The Committee met three times during the past year with poor attendance at only one meeting.

One meeting concerned itself with the approach to be taken by the Committee re adjudication of charges and fees in light of the recent FTC decisions. Upon advice of counsel, this Committee shall serve only in an advisory capacity in matters of fees.

Much time was given to a discussion relative to the use of transcutaneous nerve stimulation and the associated mechanical devices.

The Committee was also helpful in arranging a time schedule for maintaining old and new pacemakers. In this respect, some confusion has now arisen because the Fairfield County PSRO has published a similar but more liberal time schedule. It remains to be seen whether the Medicare intermediary will be compelled to adopt the PSRO system.

Several other matters to be covered in subsequent meetings already scheduled are the use of home oxygen, and the wisdom of dividing the office visit charge into a professional and technical component.

Representatives from the regional office of HEW in Boston who attended meetings of the Committee have been complimentary about our decisions.

### Committee on Legislation

*Chairman:* James W. Tierney, M.D.

*Number of Members:* 20
*Average Attendance:* 17 (including guests)

*Summary of Activities:*

Following the termination of the 1978 Legislative Session, the Committee studied the status of Tort Reform Activity in Connecticut and felt that we were in very good shape. The only change which we would like to see initiated would be the enactment of a collateral source rule and periodic payment. Such a legislative proposal has been introduced into the 1979 Legislative Session. With the opening of the Legislative Session in 1979, the Committee became very busy reviewing in excess of 150 proposed bills and determining the Society's position on those which were considered to have some bearing on the practice of medicine or on the general health of the population. Of these, we have opposed fifteen and taken positions of support on thirty-two. The remaining Bills, from our point of view, were not considered of sufficient merit pro or con to require the taking of a stand.

Samples of Bills opposed are: Proposed Bill 295, which would permit the Commissioner of Consumer Protection or his authorized agent, to remove and copy controlled substance records in the possession of practitioners, manufacturers, pharmacies and health care facilities. Bill 6591, which would require all licensed physicians in the State to participate in the insurance program of the Blue Shield Plan of Connecticut. Bill 467, which would make Herpes Simplex a reportable disease, "in the same manner as syphilis and gonorrhea." Bill 6756, to insure that the mentally ill may choose the modality of treatment they wish to receive. Bill 975, an act concerning the updating of the definition of optometry which would allow the optometrist to make usage of medication and Bill 5273, which would amend the General Statutes to provide that medical insurance benefits payable for the services of a licensed physician shall also be payable for the same services when rendered in a psychiatric clinic or community health facility by a person with a Masters Degree in Social Work.

Samples of Bills supported are: Senate Bill 6, would restore the independence of the health related licensing boards. Proposed Bill 1642, would provide peer review immunity for all proceedings of a Medical Review Committee. Proposed Bill 5306, which would expand health contracts to cover reconstructive procedures and chemotherapy required in the treatment of breast cancers and proposed Bill 938, which is the "Clean Air Act."

No report of the activities of this Committee would be complete if we neglected to comment gratefully upon the efforts of our Assistant Executive Director for Public Affairs, Frank Sweeney.

### Committee on Emergency Medical Services

*Chairman:* Edward R. Browne, M.D.

*Number of Members:* 15
*Number of Meetings:* 6
*Average Attendance:* 10

*Summary of Activities:*

**1. Ambulance Run Form**

This matter appeared on the Agenda of several of the meetings. The Committee worked in conjunction with the Office of Emergency Medical Services and also with Dr. Frazier and Miss Samons from Yale-New Haven. Several Committee members, all emergency department directors, analyzed twenty-five to fifty of the trial forms and thus became able to offer meaningful constructive criticism. A final format was decided upon—and this accomplishment resulted from a magnificent cooperation between the OEMS and Dr. Frazier and Miss Samons—and was approved. A recommendation was sent to the Council. The Council subsequently endorsed this Ambulance Run Form, which will become the format in Connecticut for compliance with Department of HEW requirements.

**2. Legislative**

It appeared from communications received from legislators and from the budget ultimately allocated to the OEMS that the Committee's support of the OEMS had been helpful.

Two proposed legislative bills were discussed during the year and recommendations sent to the referring Committees.

**3. Education Program**

No further action was taken during the course of the year relating to attempts to establish a program for school children in cardiopulmonary resuscitation. It appeared best that such be accomplished on an individual community basis.

**4. OEMS**

During the year, Mr. Chris A. Gentile was appointed Director of the Office. Mr. Gentile has attended all of our meetings. A splendid rapport has developed between the OEMS and the Committee. The Committee feels that the Office is now very capably directed and that true progress may be expected henceforth. Continuing to serve as Medical Consultant to the OEMS is C.J. Hertzler Knox, M.D., a member of our Committee and one of the original pioneers in the development of emergency medical services systems in Connecticut.

The Connecticut Advisory Council on EMS was reestablished. The State Medical Society was asked to nominate a member and the Chairman of the EMS Committee was named and confirmed as a member by Dr. Lloyd and Mr. Gentile.

**5. Statewide Plan**

The State Health Coordinating Council (SHCC) worked throughout the year to develop a State Health Plan. Mr. Robert Brunell was instrumental in keeping the Committee informed of this process, with particular emphasis on the Section on EMS. The proposed plan was reviewed by the Committee and approved at its January 30 meeting.

**6. Advanced Life Support Programs**

At the time of this writing, the Agenda for the April 10, 1979 meeting includes a discussion of the report of the Ad Hoc Committee on ALS.

**7. Passive Restraints in Motor Vehicles**

The Council endorsed the recommendation of the Committee that passive restraint systems be made available as an option in all new cars by 1984.

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## Committee on Medical Aspects of Sports

*Chairman:* Norman A. Zlotsky, M.D.

*Number of Members:* 15
*Number of Meetings:* 6
*Average Attendance:* 7

*Summary of Activities:*

The Committee has continued to be active with special mention of the following:

(1) An ongoing study of high school wrestlers with regard to hydration and percentage fat and how it affects making weight. Recommendations to CIAC for regulations based on this information were published in the latest *Connecticut Sportsmed.*

(2) *Connecticut Sportsmed* continues to be well received. Many individual physicians now request it. Our problem is still distribution to coaches. Funding only allows bulk mailing to athletic directors in hopes they will distribute the Newsletter to their coaches. We are looking for a way of being able to mail *Connecticut Sportsmed* to each coach, trainer, athletic director in the State individually.

(3) We have continued to support the athletic trainer concept for high schools. Through our efforts the School Health Advisory Council's recommendations have been revised and resubmitted to the Commissioner of Education in an attempt to obtain a recommendation for athletic trainers in middle/high schools.

(4) Recommendations for trampoline use based on the latest information available have been published in *Connecticut Sportsmed.*

(5) A number of high school inservice sports medicine programs were given by members of the Committee as well as providing speakers for more formal presentations. The annual workshop of the Connecticut Assn. of Secondary Schools on 2/15/79 was on the Sports Medicine Theme, and our Committee set up the program.

(6) A regular monthly exposure on "12 O'Clock Live" has been set up with appropriate seasonal sports topics discussed stressing prevention. Dr. Edward Tucker is coordinating this effort.

(7) In conjunction with the American Academy of Pediatrics Sports Medicine Committee, a regional advisor program is being set up assigning at least two physicians interested in Sports Medicine to each league or conference to answer questions from coaches, trainers, or administrators on such things as conditioning, nutrition, and medical problems or defects affecting eligibility. We hope this will prove to be worthwhile in getting information to the local school or individual where its needed. The Committee will be available for feedback in problem areas.

I would like to thank those active members of the Committee who have put considerable effort into the areas mentioned above as well as many other smaller details. I would especially like to thank Mr. Joseph Gordon and the Committee on Community Health of the Hartford County Medical Association for funding the cost and distribution of an issue of *Connecticut Sportsmed* to all the members of the Hartford County Medical Association. We had an enthusiastic response and are now sending copies to almost 200 physicians who were interested enough to write to CSMS and request being placed on the mailing list.

No specific recommendations are made for House of Delegates action.

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## Committee on Organ and Tissue Transfers

*Chairman:* Marion F. Baxter, M.D.

*Number of Members:* 11
*Number of Meetings:* 5
*Average Attendance:* 9

*Summary of Activities:*

This Committee continues to serve also the Connecticut State Health Department as its Sub-committee on Immunohematology. However, its major purpose is to act as an advisory body to the Connecticut Red Cross Blood Program, which has within this year changed its name to the Connecticut Red Cross Blood Services to conform to the national pattern.

During the past year, the Committee has dealt with a myriad of problems, some more complex than others.

The subject of therapeutic pheresis was discussed by the Committee because of concern about the Red Cross Blood Center becoming involved in the direct care of patients. The arguments for the Red Cross providing this service was mainly that it would be cost effective and that the Red Cross was responding to a need to supply technical aid and equipment at the request of physicians. A subcommittee was formed which prepared the appropriate guidelines for the performance of therapeutic pheresis which were reviewed and approved by the Committee as a whole with the provision for periodic review by the Medical Advisory Committee.

A discussion of criteria for granulocyte transfusion led to the appointment of a state-wide task force made up of hematologists, oncologists and blood bank directors, who, after a literature review on the subject, met on July 12, 1978 and formulated a report which was submitted to the MAC and passed on September 6, 1978 with minor modifications. The criteria for granulocytic transfusions have been distributed to blood banks and hematologists throughout the state.

The subject of a "type and screen" policy for surgical procedures was discussed in detail. Because of the great variability in institutions in the state, it was recommended that individual blood banks develop their own institutional policies based on individual previous experience. The advantages to the type and screen method may include improved inventory control, improved blood utilization in Connecticut, as well as reduction of costs of many patients.

In addition to the Medical Advisory Committee, The Red Cross has a Technical Advisory Committee made up of blood bank technologists who also meet regularly in an advisory capacity to the Red Cross. A joint luncheon meeting of the two committees was held to improve communication between the two groups.

The American Red Cross Blood Services in Connecticut applied to the American Blood Commission for recognition as an operating region. Connecticut was one of four sites selected to participate in a pre-test of the data collection instrument. Connecticut cooperated in this three-month study, providing operational data about the region. The ABC questionnaire on regional operations was reviewed by the Medical Advisory Committee and considerable concern voiced over the added labor of record-keeping in the hospital blood banks was expressed. Although there was recognition of the desirability of regional designation for purposes of Red Cross volunteer support, concern was expressed for supporting potential future government and regulatory pressure. On February 14, 1979, full recognition was granted by the ABC to Connecticut as a region for a period of two years, along with a request for a plan for increasing the participation of the transfusion services within Connecticut. The formal presentation of full recognition to Connecticut as a region will be made at the Annual Meeting of the American Blood Commission on March 15, 1979.

The chairman of this Committee, Dr. Marion Baxter, has taken a seat as a voting member of the Board of Directors of the Greater Hartford Red Cross Chapter representing the State Medical Society. Recently, she has also been asked to serve on the Blood Services Committee of the Chapter.

The increased use and cost of albumin in Connecticut is a subject of concern and the need for more information realized. Presently, a six member adhoc committee is being formed to deal with the matter and to make recommendations for the full Committee to consider.

This Committee will continue to serve in a very vital capacity to a Blood Service that is one of the best, if not the best in the country.

## The Committee to Study Perinatal Morbidity and Mortality

*Chairman:* Laura Grey Morgan, M.D.

*Number of Members:* 17
*Number of Meetings:* 7
*Number of Consultants:* 3
Dr. Joseph Warshaw, Yale Medical Center
Dr. John Raye, University of Connecticut
Dr. Joseph Baldwin, Connecticut State Health Dept.
*Average Attendance:* 50%

*Summary of Activities:*

The Committee continued its active interest in the study of case reports and summaries received from the perinatal mortality committees of hospitals throughout the state. Anonymity was preserved by deleting identifying information from the perinatal mortality and morbidity case reports. As in the past it was difficult to draw definite conclusions with regard to the management of newborns owing to the paucity of information presented in the summaries.

The Seventh Biennial Perinatal Seminar was held in the Harkness Auditorium, Yale University School of Medicine on November 8th, 1978. Yale Grand Rounds chaired by Dr. Howard Pearson of the Department of Pediatrics began the session. Invited speakers included Dr. Howard Jacobson of Rutgers Medical School who discussed maternal nutrition. Dr. Joseph Volpe of the Washington University, St. Louis, spoke on the neurological effect of perinatal asphyxia. Dr. Pamela Fitz-Harding, Professor of Pediatric, Toronto Children's Hospital, elaborated on the prognosis of low birth weight in premature infants. Dr. Irving Ladimer, of the American Arbitration Association, discussed perinatal medicine and the law. Dr. Edwin Gold, Director of Community Reproductive Health Services, at Brown University, spoke about community involvement and public education to improve perinatal care. During the 11:00 A.M. registration the Society provided refreshments for each registrant. At the conclusion of a question and answer period, there was a wine and cheese reception for the registrants. Seminar attendees are assured of five hours CME Credit. The Seminar was well attended.

Home deliveries was a topic discussed at one of the regular meetings by an active participant in this program, Dr. Richard Banfield of Stamford. Pros and cons were presented.

The Committee consensus is that the Connecticut State Medical Society continue monitoring home deliveries through its liaison with the Connecticut State Health Department without taking any conclusive stand at this time.

Note was made of a national drive to promote family centered maternity care in hospitals by the American Academy of Pediatrics, American College of Obstetrics and Gynecology, the American Nurse Association and other groups.

The Committee favors the promotion of the family centered care concept, with options such as "birthing rooms," permitting fathers as supportive figures, flexible "rooming in" and optional early release, dependent on medical advice and supervision and consistent with safety to mother and infant.

A new project brought to the attention of the Committee by Dr. Vijaya Bapat, Acting Chief, Maternal and Child Health Section of the Connecticut State Health Department, concerns a new program designated the Connecticut Improved Pregnancy Outcome Program (I.P.O.) a federally funded project. The Connecticut State Medical Society through its Perinatal Mortality and Morbidity Committee has been asked to participate. Meetings were held during the summer and fall of 1978 in Hartford with participants from the Section on Obstetrics and Gynecology of the Connecticut State Medical Society, University of Connecticut and Yale, and with clinical experts in perinatology and neonatology to discuss how the Federal funds should be allocated. Impetus for the Federal involvement and concern was a report that perinatal mortality statistics for Connecticut have not shown the steady improvement during the period 1975-1978 which had been evident prior to 1975. In spite of a decrease in infant mortality rate, Connecticut has fallen in rank from 8th to 17th nationally.

The State Society has been asked to support the I.P.O. project and to participate with the State Health Department.

The Health Department has already submitted a budget for the Federal funds, $400,000 annually for five years. Additional State funds of $150,000 have been included in the Governor's Budget for fiscal 1980 subject to Connecticut legislative approval.

The overall goal of I.P.O. is to improve the outcome of pregnancy in Connecticut. Yale University, The University of Connecticut, Danbury Hospital and Hartford Health Department are major participants. A staff consisting of a perinatologist, obstetrician, nurses, social workers and epidemiologist will carry out the following activities:

1. Review of all perinatal deaths at all 34 Connecticut hospitals.
2. Define possible preventable deaths (P.P.D.'s).
3. Determine pattern of P.P.D.'s by hospital.

Other objectives will include a demonstration project and tracking at Danbury, and an improved outreach program for high risk pregnant women at Hartford.

It is the hope of the Perinatal Mortality and Morbidity Committee that the Connecticut State Medical Society will continue its sponsorship of the Biennial Perinatal Mortality and Morbidity Seminar. To offset rising costs, perhaps a small registration fee ($10.00-15.00) should be charged all registrants.

It has been recommended to the Council that the Connecticut State Medical Society should offer through its Perinatal Mortality and Morbidity Committee support of the Connecticut State Health Department—I.P.O. project.

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## Liaison Committee With Department of Income Maintenance (formerly Department of Social Services)

*Chairman:* Charles Polivy, M.D.

*Number of Members:* 14
*Number of Meetings:* 6
*Average Attendance:* 45-50%

*Summary of Activities:*

Goals of Committee: (1) To provide quality care to the beneficiaries of this program. (2) To have more M.D. participation in caring for Title XIX patients by achieving increased payments for services to levels close to usual and customary; simplify claims processing with a more efficient and prompt reimbursement mechanism.

Within the last year distribution of an additional allocation of $800,000, from the budget of the Department of Health Services was obtained and used for ambulatory health services for the benefit of the medical provider of services in the office and hospital, with additional recommendations for changes in the reimbursement schedules for nursing home visits.

Modifications of the procedure codes for office and hospital and nursing home procedures have been discussed.

Attempts to have a new Title XIX Diagnosis Code and Procedure book published were continued with our Committee participating in a code study revision for simplification of claims processing.

PROJECT INTEGRITY (A federal investigative program by HEW) continues to create problems with Connecticut physicians. The State Department of Social Services has had to audit payments made over the past several years for various services, and audit several physicians regarding certain types of services in the utilization of office procedure codes, and nursing home visit categories. Attempts to clarify some of the misunderstandings by physicians in claims processing and coding have been explained and circularized in *Connecticut Medicine*, and various bulletins from the Department of Social Services.

Simplification of the claims processing for over 65 Title XIX patients has been achieved with the institution of the piggyback system initially requested almost three years ago.

Effective January 1, 1979, with the reorganization of governmental services, the Department of Social Services will hereafter be divided into two separate departments (1) the Department of Income Maintenance with Commissioner Maher continuing as the director of that department and (2) a new department created to care for Title XX programs under the name of the Department of Humane Services.

In order for the State Society to achieve its goals of providing high quality health care to Title XIX beneficiaries of the state, it needs the participation and support of all physicians practicing in the state.

All physicians are urged to discuss the Title XIX program shortcomings with their legislators, in order to obtain increased allocations for health services based on closing the gap between the present average payment of approximately 40% of usual and customary charges, so that Title XIX patients can obtain and be benefited by the same high quality standard of care given to other patients in the State of Connecticut. More funds and less bureaucracy are needed in the management of this program.

# PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

## OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

### EMERGENCY PHYSICIAN

Emergency Physician to join full-time group of MD's with Emergency Dept. that takes care of 34,000 patients yearly and has a paramedical program in a seashore community of 53,000 people. Contact Chairman, Emergency Dept., Milford Hospital, 2047 Bridgeport Ave., Milford, CT 06460 for salaries and benefits. Please send CV.

250 bed hospital; 40 hr. wk. Excellent backup all specialties. Attractive salary; full fringe benefits; 4 wks. paid vacation, 1 wk. paid education, Conn. license required; send CV: Thomas E. Winters, M.D., Director of Emergency Services, Bristol Hospital, Brewster Rd., Bristol, CT 06010.

### FAMILY PRACTICE

Family Practice Physician (will consider Pediatrician or Internist) for well established neighborhood clinic working 35 hours a week. Salary comparable to full-time emergency room physicians in large size hospital. Fringe benefits. Contact Gert Wallach, M.D., M.P.H., Director of Health, Waterbury, CT (203) 574-7680.

### INDUSTRIAL MEDICINE

Full-time plant physician needed by Bridgeport Manufacturer. Excellent benefit program. General practice background acceptable; internal medicine training or industrial experience a plus. Contact S. Sikorski, Employee Supt., Remington Arms Co., Inc., 939 Barnum Ave., Bridgeport, CT 06602.

Pratt and Whitney Aircraft, presently has a position available for a physician to take charge of the medical program needs of North Haven manufacturing facility. This industrial health facility has a staff of seven, one aide, a stenographer, and an insurance counselor. As physician in charge, you will work 40 hrs. per wk., with four days at North Haven, and one day at our East Hartford Medical Center for professional interchange, to participate in the executive physical examination program, and to attend staff meetings. Salary, comprehensive fringe benefits including paid malpractice insurance, license fees, professional meetings. Contact Mr. Paul R. Smith at (203) 565-7440.

### INTERNAL MEDICINE

Internist with subspecialty in Cardiology, Gastroenterology or Pulmonary to associate with established Internists in medium size community, southern New England, Hospital University affiliated. Close to shoreline, Hartford and New Haven. Abundant recreational opportunities. Send CV to CSMS to be forwarded.

### SURGERY

Openings for Surgical Residency Positions: 1-PG 1 (Salary $13,450/yr.); 1-PG 2 (Salary $14,300/yr.). Send inquiries to Dr. Joseph Belkin, Acting Chief of Surgery, New Britain General Hospital, 100 Grand St., New Britain, CT 06050

## PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

### ALLERGY

July '79. Age 32. FLEX. Am. Bds., cert.-ped. MD: India. Int., res. and fellowship: Long Island College Hosp. Wishes assoc. type practice in med. community. Contact CSMS-Allergy/YKR.

### ANESTHESIA

Oct. '79. Age 40. AB-elig. MD: Saigon Faculty of Med. Res.: Mary Hitchcock Mem. Hosp., NH. Fellowship: Dartmouth. Solo, grp. or assoc. practice in med. or sm. community. Contact CSMS/Anes.-NVN.

### DERMATOLOGY

June '80. Age 27. Conn. license. Nat'l. bds., elig. 6/80. MD: Univ. of Miami. Int.: Jackson Mem. Hosp. Res.: Baylor. Will consider all types of practice except industrial in CT. Sandy Martin, M.D., 2475 Underwood #369, Houston, TX 77030.

### INTERNAL MEDICINE

**Cardiology:** July '79. Age 32. AB-elig. MD: India. Int.: Homot Med. Ctr., PA. Res.: VA Hosp., NY. Fellowship: Beth Israel Med. Ctr., NY. Interested in invasive and non-invasive card. including nuclear card. Solo, assoc. or institutional practice desired in large or med. community. R.K. Bhalla, M.D., 353 East 17th St., #8F, NY, NY 10003.

Aug. '79. Age 27. Nat'l. bds., elig. MD: St. Univ. of NY-Downstate. Int. and res.: Brookdale Hosp., NY. Wishes solo, grp. or assoc. practice in large or med. community. Contact CSMS/IM-RC.

July '79. Age 29. Nat'l. bds., cert. MD: Georgetown. Int. and res.: Dartmouth. Also res.: Northport VA Hosp. Wishes grp. or assoc. practice. Admissions privileges to a Univ.-affil. teaching hosp. Marilyn Coruzzi, M.D., 70 Forest Dr., E. Northport, NY 11731.

**Gastroenterology:** July '80. Age 29. Conn. license pending. Nat'l. bds., cert. MD: Univ. of Michigan. Int. and res.: Thomas Jefferson Univ. Fellowship: UConn-GI. Grp. or assoc. practice in large community. Contact CSMS/IM/GAST.-IML.

**Pulmonary:** July '79. Age 32. FLEX. AB-elig. MD: Iran. Int. and res.: Danbury Hosp. Fellowship: Wayne State. Solo, grp. or assoc. practice in medium community and hosp. with at least 200 beds. Said F. Mahmoud, M.D., 20855 Lahser Rd., Apt. 606, Southfield, MI 48034.

**Hematology and Oncology:** July '79. Age 31. FLEX. AB-cert. MD: Ohio State. Int. and res.: Univ. of Oregon. Fellowship: Washington Univ., St. Louis. Wishes assoc. practice in large community. George M. Pipoly, M.D., 407 Cloisters Walk, Kirkwood, MO 63122.

Summer '79. Age 34. Nat'l. bds., elig. MD: Stanford. Int. and res.: UCLA. Wishes assoc. practice in either north/southwestern portions of CT. Wife also Internist. Michael L. Shorenstein, M.D., 1454 Yale St., #2, Santa Monica, CA 90404.

Summer '79. Age 32. Nat'l. bds., elig. MD: Stanford. Int. and res.: UCLA. Wishes grp. practice in either north/southwestern portion of CT. Husband also Internist. Rosalind G. Shorenstein, M.D., 1454 Yale St., #2, Santa Monica, CA 90404.

**Oncology:** Aug. '79. Age 33. Nat'l. bds., cert. MD and fellowship: Duke. Int.: Methodist Hosp., TX. Res.: Columbia-Presbyterian. Solo, grp., assoc. or institutional practice in large community. Interested in doing a large portion of IM as well as Onco. Carol D. Silver, M.D., 1619 Third Ave., Apt. 4G, NY, NY 10028.

May '79. Age 31. FLEX. AB-elig. Presently in practice. MD: Kyungpook Nat., Korea. Int. and res.: Mt. Sinai Hosp., Elmhurst, NY. Wishes solo, institutional or industrial practice. Contact CSMS/IM-BKY.

# Ambulatory Electrocardiogram: Diagnostic, Prognostic and Therapeutic Applications

ANDREW C. DRAKONAKIS, M.D.

**ABSTRACT—With the advent of prolonged ambulatory monitoring of the electrocardiogram, a wealth of new information is now available to the physician regarding the cardiac rhythm and its disturbances. Lack of sufficient knowledge regarding the clinical significance of cardiac arrhythmias revealed in such a dynamic setting brings up the questions of when to utilize this method and whom to treat. This review describes the spectrum of cardiac dysrhythmias revealed by this method and discusses prognostic and therapeutic implications.**

The importance of cardiac arrhythmias and their relation to specific clinical and pathologic events had not been well understood until recent technical developments allowed the continuous monitoring of cardiac rhythm. Such monitoring was first applied in Intensive-Care facilities and resulted in significant expansion of our knowledge about cardiac dysrhythmias. Further advances in technology have permitted recording and analysis of cardiac rhythm in ambulatory patients. Ambulatory monitoring refers to the method of electromagnetic tape recording of electrocardiogram (EKG) over prolonged periods and is used for diagnostic and prognostic purposes and for evaluation of antiarrhythmic therapy.

### Diagnostic

Evaluation of symptoms of cardiac palpitations is best achieved by prolonged ambulatory monitoring. Occasional patients with seemingly innocent cardiac palpitations may be found to have complex arrhythmias by ambulatory monitoring. Conversely, many patients may be saved from prolonged, expensive and often risky medical treatment when continuous monitoring reveals no disturbance of cardiac rhythm at the time of complaints of palpitations. The longer the duration of monitoring the more individuals will be found to have arrhythmias.[1-3] Thus, among patients with known coronary heart disease, 10-14% will have PVCs on a random—1 minute long—EKG recording, while nearly 90% of them will exhibit some ventricular ectopic activity on 24 hour monitoring.[1]

Atypical or Prinzmetal Angina Pectoris may be documented if EKG changes, such as marked ST-segment depressions or ST-elevation or varying degrees of atrio-ventricular block, occur during pain. Although some uncertainty still exists regarding the diagnostic significance of ST-segment and T-wave changes, current devices appear to yield reliable results since they have improved frequency responses, meeting the specifications of the American Heart Association. Thus, good correlation of ambulatory monitoring with submaximal exercise testing (Wolf et al.)[4] and with coronary angiography (S. Stern)[5] has been found, in regards to ST-segment changes. Conversely, Crawford et al.[6] found the specificity of the ambulatory monitoring to be significantly lower to exercise testing (61% vs. 75%), while its sensitivity was only slightly inferior (62% vs. 67%). Thus, minor ST-depressions of less than 1 mv. are probably insignificant, whereas major ST-depressions, especially when accompanied by symptoms, are probably reliable evidence of heart disease.

Cardiac dysrhythmias have been found by ambulatory monitoring to cause neurologic syndromes such as transient cerebral ischemic attacks[7-9] and occasionally to masquerade idiopathic epilepsy.[10]

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ANDREW C. DRAKONAKIS, M.D., Director Cardiac Rehabilitation, West Haven V.A. Medical Center.

Address Reprint Requests to: West Haven V.A. Medical Center, West Haven, CT 06516 (Dr. Drakonakis).

Ambulatory monitoring has provided new information about the occurrence of dysrhythmias in subjects with cardiac syndromes such as: mitral valve prolapse (MVPS), idiopathic hypertrophic subaortic stenosis (IHSS), preexcitation syndromes, sinus node dysfunction and chronic pulmonary disease.

Cardiac dysrhythmias are very common even among asymptomatic patients with MVPS. Frequent PVCs and complex ventricular arrhythmias are found in about 50%, atrial arrhythmias in 35%, and serious brady-arrhythmias in 29%, while only 16-25% of such patients are free of arrhythmias.[11] [12]

Patients with IHSS have a high incidence of cardiac dysrhythmias previously unsuspected.[13] [14] R. Ingham[13] found PACs in 96% and PVCs in 89% of patients with IHSS. Frequent PACs and PVCs were present in 49% and 25% of the patients respectively; 70% had episodes of supraventricular tachycardia, including paroxysmal atrial fibrillation, while 7% of patients had episodes of ventricular tachycardia. Of interest was the finding of very poor correlation between symptoms and recorded dysrhythmias. These findings are further supported by a study of 26 patients, victims of sudden death with known but asymptomatic IHSS, by Maron et al:[14] various atrial and ventricular arrhythmias were found on some of these patients; two had documented episodes of atrial tachyarrhythmias, and in four patients ventricular fibrillation was documented shortly after their collapse. The authors made the suggestion that rapid supraventricular tachycardias may be causally related to sudden death in such patients by the mechanism of inadequate ventricular filling—increased left ventricular outflow obstruction—hypotension—cardiac arrest.

Pre-excitation syndromes are associated with increased incidence of cardiac dysrhythmias, usually re-entrant tachyarrhythmias. Isaeff et al.[15] found that 5 out of 20 symptomatic patients with Wolf-Parkinson-White syndrome (WPW) had multiple episodes of PAT and one patient had paroxysmal atrial fibrillation during 10 hours of ambulatory monitoring. The incidence, however, of dysrhythmias in asymptomatic patients with this syndrome is not known and symptoms of palpitations may be misleading. Hindman et al.,[16] studying 27 unselected patients with WPW, found no episode of supraventricular dysrhythmias during 24 hour monitoring, while sinus node dysfunction and episodes of intermittent pre-excitation were common. Poor correlation of symptoms was seen in 8 patients who had negative tape recordings at the time of complaints of palpitations. Patients with WPW and intermittent atrial fibrillation appear to be at high risk of developing ventricular fibrillation if the ventricular response is very rapid and the patient is on digitalis.[17] Thus, the finding of unsuspected intermittent atrial fibrillation with rapid ventricular response in patients with WPW should be an indication against digitalis use.

Lown-Levine-Ganong Syndrome (LLGS), characterized by short P-R interval and normal QRS duration, is considered a form of pre-excitation syndrome and is often associated with regular, supraventricular tachycardia with narrow QRS complexes. Ventricular arrhythmias and atrial fibrillation, however, are also frequent.[18]

Concealed WPW syndrome is often associated with paroxysmal supraventricular tachyarrhythmias, including atrial flutter and fibrillation. This syndrome, characterized by normal QRS pattern, is due to the presence of accessory bypass tracts capable of only retrograde conduction[19] [20] or to other mechanisms involving re-entry in the sinus node, the atrium or the A-V node including dual A-V nodal pathways.[21] [22]

Sinus node dysfunction (SND) is more frequent in the elderly but occurs also in young adults and in children with and without associated congenital cardiac defects.[23] [24] Adult patients with SND frequently have abnormalities of the conduction system and generalized depression of subsidiary cardiac pacemakers which probably contribute to their symptomatology by the occurrence of prolonged asystolic periods. Sinoatrial exit block appears to be a frequent mechanism in this disorder. SND in the elderly presents usually in three forms:[25] (1) symptomatic bradycardia (sinus arrest, sinoatrial block, severe sinus bradycardia), (2) brady-tachycardia syndrome (paroxysmal atrial fibrillation, atrial flutter, PAT), (3) patients in whom pharmacologic treatment either with digitalis or with antiarrhythmic drugs brings out symptomatic bradycardia.

Patients with atrioventricular and intraventricular conduction defects (first and second degree A-V nodal block, bifascicular block) frequently have symptoms of syncope. While syncope in such patients may be due to etiologies other than transient heart block such as CNS disease, IHSS, aortic stenosis, postural hypotension, etc., ambulatory monitoring may prove most useful in such patients if advanced degrees of A-V block, prolonged asystolic periods or cardiac tachyarrhythmias are revealed, thus making unnecessary further sophisticated electrophysiologic studies which are often of limited value.[26-28]

Patients with severe chronic obstructive pulmonary disease (COPD) have frequent cardiac arrhythmias. Thus, COPD patients were found to have increased incidence of atrial and ventricular arrhythmias compared to normal subjects by Kleiger and Senior.[29] In the same study the incidence and severity of ventricular dysrhythmias among COPD patients were similar to patients recovering from myocardial infarction, while the former had more atrial arrhythmias. The prognostic significance of the arrhythmias found in COPD patients has not been established; however, since the incidence of sudden "unexplained death" appears to be high in such patients,[30] the possibility of cardiac dysrhythmias as the primary etiology of death deserves further investigation.

Intermittent cardiac pacemaker malfunction not evident on standard EKG may be documented by ambulatory monitoring.[31]

Ambulatory monitoring is very useful in documenting various dysrhythmias, and in some instances may indicate the need for cardiac pacemaker. Further sophisticated electrophysiologic studies may be indicated in refractory cases of arrhythmias for the delination of their mechanism and evaluation of the protective effect of antiarrhythmic drugs.[22]

### Prognostic

Identifying patients who are at high risk for sudden death is of major importance and a very difficult task. Many studies have borne out a relationship between ventricular ectopic activity and subsequent sudden death in patients with coronary artery disease.[3, 32-44] In the Tecumseh, 6-year-follow-up epidemiologic study,[34] the prevalence of manifest coronary heart disease and the incidence of sudden death were significantly higher (the latter by six-fold) for the subjects who had PVCs on resting EKG. Hinkle[35] et al. using 6 hour ambulatory monitoring found that the risk of sudden death during 5 year follow-up was significantly greater for subjects with more than 10PVCs/1000 heart beats. Of interest is that 83% of patients who subsequently died of coronary heart disease had PVCs on ambulatory monitoring yet only 20% showed PVCs on standard EKG. The Coronary Drug Project Research Group[37] has shown that the presence of PVCs on a routine EKG in males who have recovered from M.I. doubles their risk for sudden death despite the known insensitivity of routine EKG in detecting arrhythmias.

The prognostic significance of PVCs has been emphasized by studies using ambulatory monitoring in the 2 week to 3 month period following myocardial infarction. Several such studies have found a striking higher incidence of sudden death among patients with significant ventricular ectopy compared to patients who were free of PVCs.[38-42] It appears that cardiac dysrhythmias occurring during the acute phase of myocardial infarction and observed in the Coronary Care Unit do not influence the prognosis following hospital discharge while the presence of PVCs detected by ambulatory monitoring just before hospital discharge correlates significantly with post-hospital sudden death.[44]

The detection of PVCs is related to the duration of monitoring and the age of the subjects. About 50-60% of random middle-aged individuals and nearly 90% of patients with known coronary artery disease exhibit PVCs on 24 hour monitoring.[1, 35] Hinkle[3] found among actively employed males that the incidence of PVCs increased with age; thus PVCs were found in 19% of those ages 35-40, 69% of those ages 55-60, and 80% of those ages 60-65.

Certain features of PVCs such as frequency, QRS morphology, widened QRS, multiformity, repetitive patterns, salvos of 2 or more, and degree of prematurity have been considered to carry particular prognostic significance. PVCs of extreme prematurity have been considered to be associated with high incidence of ventricular fibrillation since the so-called R on T phenomenon (R/T) was first described by Smirk in 1949.[32] Since then, many other studies have supported the general notion that frequent PVCs or complex ventricular arrhythmias are harbingers of sudden death in patients with coronary artery disease.[1, 32-44] This concept was challenged, however, by a recent study where the so-called warning arrhythmias and the R/T phenomenon were found to be poor predictors of ventricular fibrillation in patients with acute myocardial infarction.[45] The authors suggested therefore the prophylactic use of antiarrhythmic therapy once an acute ischemic episode is suspected without reliance on the presence or absence of "warning arrhythmias." Another recent study also suggests that the danger of sudden death in patients with ventricular tachycardia (3 beats or longer) detected by ambulatory monitoring in the post-hospital phase of myocardial infarction is not as high as has been generally accepted.[46]

Despite the existing uncertainty regarding the clinical significance of PVCs, several groups of patients can be identified as being at high risk for sudden death and where antiarrhythmic treatment appears to be justified. In this respect the classification of ventricular arrhythmias proposed by Lown[36] is very useful (Table 1). Table #2 lists in order of importance indications for antiarrhythmic therapy. Patients already resuscitated from ventricular fibrillation appear to have a 30% chance of recurrent bouts of V.F. at a median time of 20 weeks.[47] That antiarrhythmic therapy may be beneficial in such patients is

Table I

GRADING OF VENTRICULAR ARRHYTHMIAS

| | | |
|---|---|---|
| GRADE 0 | | No ventricular arrhythmias |
| GRADE 1 | | Isolated PVCs less than 30 hour |
| | 1a | less than one/minute |
| | 1b | more than one/minute |
| GRADE 2 | | Frequent isolated PVCs more than 30/hour |
| GRADE 3 | | Multiform isolated PVCs |
| GRADE 4 | | Repetitive PVCs |
| | 4a | couplets |
| | 4b | salvos |
| GRADE 5 | | Early PVCs (R on T phenomenon) |

Table 2

ASYMPTOMATIC PVCS JUSTIFYING MEDICAL TREATMENT

1. Patients resuscitated from primary ventricular fibrillation
2. Patients with recent myocardial infarction and PVC grade $\geq 2$.
3. Patients with current angina and PVC grade $\geq 2$
4. Angina free patients but with known or suspected coronary heart disease who have PCV grade $\geq 4$

suggested by the finding of significant decrease in the incidence of sudden death in treated patients compared to non-treated patients despite the lack of demonstrable supression of cardiac arrhythmias by repeated prolonged monitoring.[48] Patients with recent myocardial infarction or current angina and frequent PVCs or complex ventricular dysrhythmias should probably also be treated.

The natural history of chronic conduction defects (Bifascicular Blocks) remains unclear and the prognosis appears to depend upon the extent of ischemic heart disease and the degree of heart failure.[25-27] Since the incidence of progression to complete heart block appears to be only about 2% per year, ambulatory monitoring cannot be expected to give significant prognostic information in asymptomatic patients. Electrophysiologic studies appear to have also limited prognostic value in this condition. The predictive value of a prolonged infranodal conduction time (H-Q interval) is questionable.[25-27] A study by Scheinman et al.,[28] however, suggests that marked prolongation of H-Q interval ($\geq 70$ msec) in patients with neurologic symptoms is associated with a high risk of progression to complete A-V block. Electrophysiologic studies in symptomatic patients, therefore, are indicated when prolonged continuous electrocardiographic monitoring fails to reveal significant A-V block.

Patients with congenital heart block, even in the absence of associated congenital cardiac defects and despite the supra-Hissian location of the block, were found to have frequent bradyarrhythmias and tachyarrhythmias by prolonged monitoring. Patients at increased risk of developing Adams-Stokes attacks or sudden death may be identified by ambulatory monitoring.[49]

The importance of dysrhythmias detected with Holter monitoring should be assessed taking in consideration the incidence of such dysrhythmias in the normal population and the clinical setting in which they occur. While frequent and complex tachyarrhythmias are rare among normal subjects, bradyarrhythmias appear to be fairly common.[12, 50-53] Thus, Brodsky, et al.[52] found that 24% of male medical students had frequent episodes of marked sinus bradycardia during rest and sleep, with heart rates of 30-40/minute, while prolonged sinus pauses of 1.5-2.06 seconds were present in 68% of the students. First and second degree A-V block of Mobitz type I were found in 8% and 6% respectively.

When the above arrhythmias are encountered among young normal subjects, they are probably benign and do not require treatment; similar dysrhythmias, however, occurring in the setting of ischemic heart disease or cerebrovascular atherosclerosis may carry serious prognostic implications. It should also be noted that unsuspected cardiac dysrhythmias may be found among apparently normal subjects who may have, however, significant silent coronary artery disease.[35 53]

The incidence of sudden death is increased among patients with MVPS[54 55] and patients with IHSS,[13 14] and evidence in the literature suggests that many of these deaths are related to cardiac dysrhythmias.

While the prognostic significance of cardiac dysrhythmias found in patients with ischemic heart disease appears to be established, the significance of cardiac dysrhythmias in other cardiovascular conditions and in the apparently normal population remains unclear. Furthermore, it remains yet to be proven that antiarrhythmic treatment alters the prognosis beneficially. A few recent studies, however, appear to bring some optimism. Thus, as mentioned above, the prognosis of patients resuscitated from ventricular fibrillation was improved with antiarrhythmic therapy.[48] A few recent studies also have shown improvement in prognosis after myocardial infarction by treatment with b-Adreno-receptor blocking drugs.[56-58]

Table 3

ACTIVITIES TO BE MONITORED

1. Activities of Daily Living and Sleep
2. Recreational: Walking, Jogging, Golf, Bicycling, Bowling, etc.
3. Sexual Intercourse
4. Return to Work

### Evaluation of Therapy

Ambulatory monitoring is very useful in evaluating the effectiveness of antiarrhythmic treatment and in making appropriate adjustments of drug regime. In this respect, the half-hour continuous monitoring while the patient is waiting in the doctor's office or sent for a 10 to 15 minute walk appears more practical than 24 hour monitoring.[1]

The large spontaneous variations in arrhythmias and their poor reproducibility pose serious problems in evaluating the efficiency of antiarrhythmic drugs. Thus, spontaneous increases in the number of PVCs of up to several hundred per cent and spontaneous reductions in the range of 50-90% were found frequently by Winkle et al;[59] the reproducibility of complex PVCs on repeated monitoring appears to be only about 40%.[1] Despite these shortcomings, repeated prolonged ambulatory monitoring remains the only available objective way for evaluating antiarrhythmic drug effect.

Continuous recording over 24 hours may help establish a diurnal pattern of the incidence of dysrhythmia in some patients.[60 61] Treatment may then be adjusted on that basis so that adequate therapeutic blood levels of the antiarrhythmic agent coincide with peak incidence of arrhythmia. Although the frequency and complexity of PVCs are decreased during sleep in most subjects, a small number of patients (about 8%) may exhibit the opposite.[2, 60-61] Particularly, bradyarrhythmias and A-V block may be identified with monitoring during sleep.

Use of ambulatory monitoring in patients undergoing physical training may reveal unsuspected serious arrhythmias requiring adjustment of antiarrhythmic regime.[62]

The occurrence of cardiovascular complications—including death—in patients undergoing active physical training in exercise rehabilitation programs was found lower when the electrocardiogram was continuously monitored during exercise.[63]

## Summary

Prolonged ambulatory monitoring of EKG has brought to light an abundance of new information the clinical significance of which is largely unknown. Given the enormous number of individuals exhibiting dysrhythmias, the physician faces the dilemma of whom to treat and when to utilize the method of ambulatory monitoring. Unnecessary utilization adds to the expense and the disclosure of the finding of cardiac dysrhythmias may psychologically harm the patient. Even more important, unneeded medical treatment is not only costly, but may be dangerous and, in fact, there is evidence that more serious arrhythmias and even death may result from the available medications.

In patients with troublesome symptoms the utilization of ambulatory monitoring for diagnostic purposes is apparent. When such symptomatic patients are found to have significant arrhythmias that may reasonably explain their symptoms, the need for medical or pacemaker therapy is also apparent.

Significant information is available relating the occurrence of sudden death to the existence of significant ventricular ectopy in the early post-myocardial infarction phase. In view of the recent reports on the improvement of prognosis following myocardial infarction or primary ventricular fibrillation, with the use of antiarrhythmic treatment in out-of-hospital patients and the experience from the coronary care units, where mortality from acute myocardial infarction has been decreased mostly by effective antiarrhythmic treatment, the routine use of ambulatory monitoring appears justifiable in all patients recovering from acute myocardial infarction.

The use of ambulatory monitoring and the indications for treating arrhythmias in asymptomatic patients suspected or known to have coronary artery disease or other cardiac pathology such as mitral valve prolapse syndrome or asymmetric septal hypertrophy remains unsettled.

Ambulatory monitoring appears to be the only objective way for evaluating drug effectiveness despite the shortcomings mentioned above. Continuous technologic improvements already underway will result in the extraction of more precise information becoming more readily available to physicians.

The main limitation, therefore, of ambulatory monitoring appears to lie not in the method itself but in the lack of sufficient knowledge regarding the clinical significance of the many dysrhythmias being revealed and the uncertainty regarding the choice of drugs and efficacy of pharmacologic treatment.

The wealth of information being provided by this new technique, which presently appears to be overwhelming to the physicians, is certain to increase our understanding of cardiac arrhythmias in a dynamic and functional sense previously not available and contribute to the future management of patients.

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# Salmonella Typhi Urinary Tract Carrier in a Mental Hospital

LUDMIL CHOTKOWSKI, M.D.

Communicable disease, particularly involving the enteric and urinary tracts, has traditionally been a matter of great infection control concern in mental hospitals where proper personal toilet hygiene is often not practiced.[1] The finding of a Salmonella typhi urinary tract carrier state in a long term mental patient residing in Connecticut Valley Hospital, without spread of the infection, suggests that such a circumstance need not necessarily be catastrophic.

## Case Report

A 64-year-old white male schizophrenic was serendipitously found to have an S. typhi urinary tract infection on routine cultures taken before and after a 24-hour catheterized VMA analysis, during the investigation of his hypertension. Both cultures were originally reported erroneously as Shigella boydii by the local and state laboratories. The specimen sent to the Communicable Disease Center in Georgia for subtyping was, however, reported as Salmonella typhi, and later verified by the initial laboratories. The patient, like many typhoid carriers, had no history to suggest an acute episode of typhoid fever, either recently, or in the past in Italy, the country of his birth.[2]

On the basis of the Shigella report, initial treatment in this case consisted of ampicillin 1 gram daily for 16 days. At the end of this time, two ampicillin resistant organisms were cultured in significant urinary colony counts, namely Citrobacter freundii and Pseudomonas aeruginosa. However, one month later a follow-up urinary culture was again reported as Shigella (later to be confirmed as S. typhi) with a colony count exceeding 100,000 organisms. The patient was then placed on triple drug therapy in view of the failure of the one drug approach, and because of the sensitivity findings on those two new organisms. The regimen consisted of daily doses of ampicillin 2 grams, tetracycline 1 gram and Bactrim (trimethoprim .64 gram and sulfamethoxazole 3.2 grams). This was given without side effects for 21 days. Six subsequent urine and three stool cultures were all negative two months after completion of this antibiotic therapy. On the basis of these cultures, the urinary tract typhoid carrier state was presumed successfully terminated. Had it been known that the urine culture was S. typhi, large dose ampicillin, or amoxicillin would have probably been the drug of choice.[3]

During the period of treatment, the patient was isolated in a single room under urine and stool precautions. He frequently urinated in the bed, on the floor, in his trousers, in wastebaskets, or in the toilet bowl. He was also incontinent of feces. Three stool cultures were taken during his illness and at no time were they positive. The cleaning disinfectant used in Connecticut Valley Hospital is called Hospital Sage, containing 10% available chlorine and a phenol coefficient of 43 for S. typhi. It is notable that no cases of typhoid fever occurred in the hospital throughout this patient's entire intermittent stay of 43 years.

During therapy, an intravenous pyelogram was performed showing right nephrolithiasis. A routine urine specimen showed specific gravity of 1011, PH 5.5, RBC 2 to 3, WBC 30 to 40, and negative urobilinogen, bilirubin, ketone, sugar and protein. Blood studies showed BUN 13, normal CBC, negative serology. Post-treatment urine showed reduction in WBC to normal.

## Discussion

The case report of a urinary typhoid carrier state in a mental institution is described. Typhoid urinary tract carrier states are relatively uncommon and are said to occur usually in diseased kidneys or in obstructed urinary tracts such as in schistosomiasis.[4] [5] Treatment in this case was complicated by the fact that an erroneous urinary tract culture was reported and the patient was treated for Shigella with low dose ampicillin instead of the usual larger doses of ampicillin or amoxicillin. A 100% success rate in 12

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urinary carriers treated with amoxacillin has been reported.[4] Bactrim successfully cleared 17 of 19 Salmonella carriers in another similar study.[5]

Although the duration of the carrier state was unknown in this patient, it probably did exist for a fairly long period of time in view of the presence of chronic nephrolithiasis. It seems, therefore, that such a condition in an incontinent patient in a mental institution can exist without necessarily a concomitant outbreak of typhoid fever. The reason for this may be that typhoid fever infection is felt to be dose related and hence more common following the ingestion of innoculated food or contaminated drinking water where the number of organisms is large. There is evidence from human volunteer studies that ingestion of as few as 10 organisms can initiate infection. On the other hand, in these volunteers only 50% developed typhoid fever after oral ingestion of as many as 100 million viable organisms. Infectivity is thus felt to be related to strain virulence and those volunteers not developing symptoms ingested less virulent strains.[2]

According to our State Public Health Code standards, acute cases of typhoid fever "shall not be released from isolation until free from infection and shall not be considered free from infection until a series of laboratory examinations consisting of at least three successive specimens of feces and three successive specimens of urine, taken at intervals of not less than 48 hours apart, are negative. Such cases shall not be released from public health observation until a repeated series at three months and another at six months intervals are similarly found to be negative."[6] At the present time there are some 50 typhoid carriers in Connecticut[7] and an estimated 2,000 or more in the United States,[8] not tabulated as to urinary or enteric, but probably mostly enteric. This is apparently a miniscule number when compared to those countries with poor sanitation and polluted food and water.

## Conclusion

The urinary tract typhoid carrier state is a relatively rare finding, and is usually found in conjunction with pre-existing urinary tract disease such as schistosomiasis. This patient had nephrolithiasis.

Communicable disease of any type, but particularly of the urinary and enteric tract, in a mental hospital setting where proper toilet hygiene is often not practiced, is traditionally a matter of great concern in respect to rapid spread of infection. However, despite a high urinary colony count and despite urinary incontinence in this mentally ill patient, no spread of typhoid fever occurred. The reason for this is speculative but may either be a reflection of adequate use of chlorinated floor cleanser, or of course, a fortuitous event.

The carrier state was successfully terminated with an unusual course of triple antibiotic therapy which included Bactrim, known to be effective as an alternative drug to ampicillin or amoxicillin, although ampicillin is listed as the drug of choice for this purpose.

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# Ultrasound and Computed Tomography in Obstructive Jaundice

RICHARD A. SORGEN, M.D. AND DAVID I. ROBBINS, M.D.

## Case Report

A previously healthy 63-year-old white male was admitted for evaluation of painless jaundice of two weeks' duration.

There was an eight pound weight loss associated with dark urine and light stools. The patient had one previous episode of jaundice at age 40. He was a liberal drinker and had smoked two packs of cigarettes per day for many years.

Physical examination revealed a grossly icteric man. There was moderate hepatomegaly and a separate, firm, non-tender and non-pulsatile mass in the epigastrium. The stool was clay-colored.

Pertinent laboratory data include the following: serum amylase, albumin, total protein and LDH were all normal; total bilirubin 38.0 (0.2-1.0 mg/dl.); SGOT 86 (5-25 I.U./L.); SGPT 136 (3-20 I.U./L.); alkaline phosphatase 402 (25-70 I.U./L.); WBC 11,600; HCT. 36.0. The blood sample was grossly icteric and urinalysis showed a 3+ bilirubin.

Ultrasound of the abdomen was performed. The gallbladder was distended and contained non-shadowing "sludge" (Figure 1A). The liver displayed no focal abnormality. However, the intrahepatic and common bile ducts were dilated (Figures 2, 3A). The distal common bile duct and pancreas were obscured by gas. The findings indicated extra-hepatic obstruction of the biliary tree.

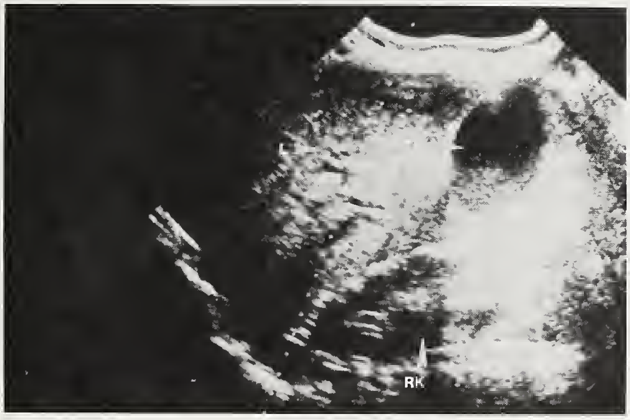

Figure 1A
Longitudinal section, right of midline
G.B. = distended gallbladder with non-shadowing sludge.
L = liver
R.K. = right kidney

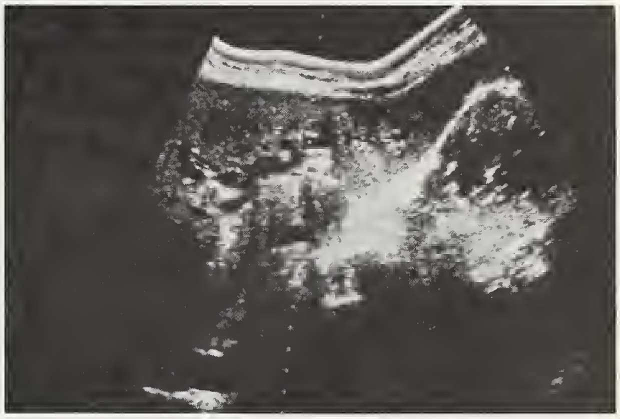

Figure 2
Longitudinal section, right of midline
Note branching pattern of dilated intra-hepatic biliary radicles

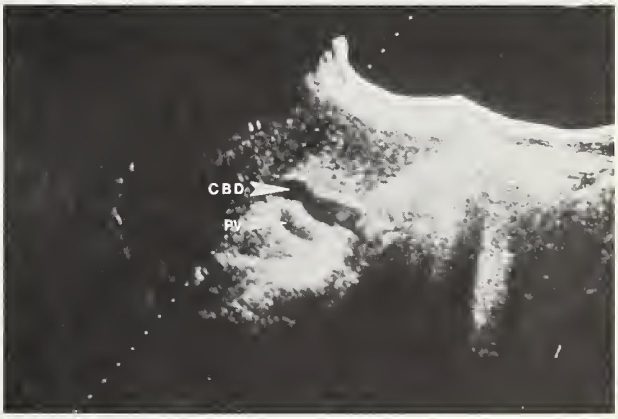

Figure 3A
RAO position
CBD = dilated common bile duct
PV = portal vein

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On examination by computed tomography, the gallbladder was enlarged (Figure 1B). While intra-hepatic biliary dilatation was equivocal, the study clearly demonstrated a lobulated mass in the region of the head of the pancreas, surrounding a dilated common bile duct (Figure 3B).

At surgery, the pancreatic head was firm and enlarged, and there was invasion of peri-choledochal nodes by tumor. The liver and gallbladder were congested, while the common bile duct measured 2 cm. Biopsy of a node yielded moderately well-differentiated adenocarcinoma. Cholecysto- and gastrojejunostomies were performed.

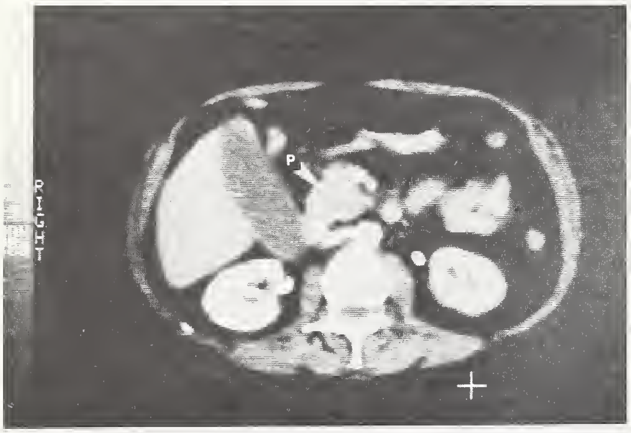

Figure 1B
10 cm. below xiphoid; p.o. and i.v. contrast given
GB = distended gallbladder of bile density
P = enlarged head of pancreas

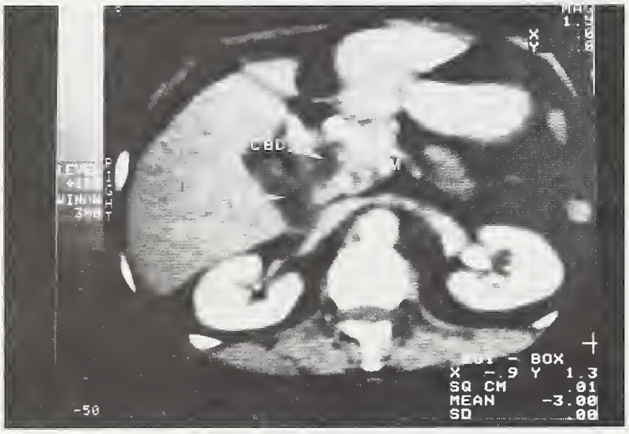

Figure 3B
7 cm. below xiphoid. After contrast.
GB = gallbladder
CBD = common bile duct (dilated)
M = mass representing enlarged peri-choledochal nodes

## Discussion

This case illustrates classic sonographic and CT findings in obstructive jaundice. As Taylor and Rosenfield have pointed out,[1] ultrasound is a highly accurate method of establishing the presence of biliary tree dilatation. The intra-hepatic radicles are imaged as branching, tubular structures that are dilated in extra-hepatic obstruction. In the RAO, or, right anterior oblique position, the dilated common bile duct may be seen anterior to the portal vein, bowing convexly towards the anterior abdominal wall.[2]

The presence of a dilated gallbladder, accompanied by common bile duct dilatation, suggests either distal choledochal or pancreatic pathology. However, ultrasonographic assessment of this region may be limited by bowel gas.

The role of computed tomography in obstructive jaundice is to delineate a pancreatic lesion which is obscured on ultrasound. As Shanser et al have recently pointed out, CT need not demonstrate intra-hepatic biliary dilatation in the clinical setting of obstructive jaundice. Rather, a dilated common bile duct in association with a pancreatic mass are convincing evidence of extra-hepatic obstruction. Our case corroborates their report.

Our pre-operative diagnosis was entirely non-invasive and accurately defined the anatomic abnormalities. Had CT shown no pancreatic pathology, transhepatic cholangiography in search of choledochal tumor, stones or fibrosis would have followed. We feel that ultrasound and computed tomography should be the initial modalities in the diagnostic evaluation of obstructive jaundice.

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# Leiomyoma of the Esophagus

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**ABSTRACT—Seventeen cases of leiomyoma of the esophagus were reviewed to determine the accuracy of the diagnosis and success of treatment. There were 12 females and 5 males. The most common symptom seen in 13 of 17 patients was dysphagia. The average age was 44 years with a range from 6 to 66 years. Four patients were asymptomatic and had the diagnosis made because a radio-opaque density suspicious of tumor was present on radiograph of the chest or because a barium esophagram was performed for other gastrointestinal symptoms. Eight patients had an incorrect preoperative diagnosis. Three of these had barium contrast studies that were interpreted as stricture with hiatus hernia, two were diagnosed as reduplication cyst, and one was thought to have diffuse spasm of the esophagus. There was one each of achalasia, neurilemoma and hiatus hernia with an esophageal ring. A high association with hiatus hernia was seen in this series (8 cases). Leiomyoma of the esophagus is an uncommon disease and does not always present in the standard fashion. This paper reports some unusual presentations of this disease and discusses the difficulties in diagnosis and treatment.**

## Introduction

Although leiomyoma of the esophagus is the most common benign esophageal tumor, its incidence is low. As a result few physicians have sufficient experience to become familiar with its diagnosis and treatment. Most textbooks only casually mention the diagnosis of esophageal leiomyoma and imply it is easily made.

Our review of the records of three teaching hospitals (Yale-New Haven Hospital, Hospital of St. Raphael, and Waterbury Hospital) representing approximately 1500 beds yielded only 17 cases and in 8 of the cases the diagnosis was unsuspected or incorrect preoperatively. Hence, the surgeon must be prepared to recognize the signs, symptoms and associated lesions of benign esophageal leiomyoma and be prepared to treat it properly when confronted with it unexpectedly in the operating room.

## Materials and Methods

The records of the Yale-New Haven Hospital and two affiliated hospitals (Hospital of St. Raphael and Waterbury Hospital) were reviewed for the period 1962 to 1977, resulting in identification of 17 cases of surgically treated leiomyoma of the esophagus. These patients underwent 18 operations, representing the experience with this disease of eight thoracic surgeons. Five patients treated in the last 18 months of the study prompted this review of experience with leiomyoma of the esophagus.

## Results

There were 12 females and 5 males; the average age was 44 years with a range from 6 to 66 years. All patients had barium esophagrams and 11 had esophagoscopy as part of their preoperative work-up. In spite of this the diagnosis was unsuspected or incorrect on 9 out of 18 occasions. Three patients were thought to have hiatus hernia with stricture, two were diagnosed as having a reduplication cyst, one as diffuse spasm of the esophagus, one as achalasia, one

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as a neurilemoma and one as a hiatus hernia with an esophageal ring.

Hiatus hernia was associated with leiomyoma of the distal esophagus in eight cases and in four of these cases the leiomyoma was not diagnosed preoperatively but was found at operation and explained the x-ray findings and symptoms. One patient had removal of the leiomyoma and closure of the crux of the diaphragm but had recurrent hiatus hernia symptoms necessitating a Nissen fundoplication one year later.

Dysphagia was the most common symptom having been noted in 13 out of 17 patients. Four patients had no esophageal symptoms and had the diagnosis made during evaluation of other gastrointestinal complaints. Four had a mediastinal mass identified on routine chest film. One patient, a 24-year-old female with an esophageal mass and rheumatic mitral stenosis, underwent closed mitral valvulotomy and simultaneous removal of a leiomyoma, both via a left thoracotomy.

## Case Reports

**Case 1:** A 64-year-old white female was seen because of cervical dysphagia. A chest film demonstrated a calcified mass at the base of the neck. Barium swallow demonstrated compression of the esophagus. A firm calcified leiomyoma was enucleated from the esophagus through a cervical incision. The patient has remained asymptomatic since operation.

**Case 2:** A 44-year-old asymptomatic man had a posterior mediastinal mass with appearance typical for leiomyoma on chest roentgenogram four years prior to admission for which no operation was recommended. On the radiograph taken two weeks prior to admission the mass appeared enlarged. A barium swallow was normal. Through a left thoracotomy a 6 x 2 cm bilobular tumor surrounding the distal esophagus was easily enucleated.

**Case 3:** A 54-year-old white female with dysphagia for 11 years was originally diagnosed as having achalasia. She underwent distal esophageal dilatation twice with a Mosher bag with mild temporary relief of symptoms in 1974. A barium swallow was read as "Asymmetrical gastric esophageal junction, question of epiphrenic diverticulum and secondary and tertiary contraction. The diagnosis: Diffuse spasm of the esophagus." Esophagoscopy demonstrated "firmness of the distal esophagus and dilated proximal esophagus." She underwent a left thoracotomy with a diagnosis of diffuse spasm of the esophagus. A long myotomy of the esophagus was performed. When the gastroesophageal junction was reached, a firm tumor was found encircling the lower esophagus. This was removed, and she has remained asymptomatic.

**Case 5:** A six-year-old girl was evaluated for recurrent upper respiratory tract infection. Her chest film revealed an upper mediastinal mass and subsequent barium swallow demonstrated a compressing mass in the upper mediastinum between the esophagus and trachea. A diagnosis of reduplication cyst was made. Through a right thoracotomy she underwent a difficult removal of a 45 gram 8 x 8.5 cm. mass of leiomyoma. Postoperatively she had difficulty swallowing and barium esophagram in the early postoperative period demonstrated delay in emptying. She was discharged taking primarily a liquid diet and followed until 1978 when a repeat barium swallow was interpreted as achalasia. Repeat surgery through a left thoracotomy demonstrated diffuse leiomyomatosis of the esophagus. During surgery some of the bulky tumor was removed and a long esophageal myotomy was performed. Short term follow-up on this patient reveals excellent symptomatic relief.

## Discussion

Although multiple leiomyomas,[1, 2, 3] diffuse leiomyoma,[5] and giant leiomyoma[6, 7, 8] of the esophagus have been reported, the lesion is usually single (97% of cases) and located in the lower third of the esophagus 50 to 60% of the time,[9, 10] followed by the middle third and rarely the upper esophagus where striated muscle is more common. Multiple leiomyomas are variable in their location.

The vast majority of these tumors are intramural and only rarely are they polypoid or extra-esophageal.[9] Although frequently thought to be characteristically horseshoe-shaped, only 10% of them have been reported as such by Peabody, *et al,* in an analysis of 838 cases.[9]

The majority of esophageal tumors are malignant and the importance of making the correct diagnosis of a benign leiomyoma to determine surgical therapy is obvious. Malignant transformation to leiomyosarcoma of these tumors is fortunately rare.

When making the diagnosis of leiomyoma of the esophagus, symptoms may be nonspecific and misleading. Dysphagia, pain and pyrosis are most frequently seen. These symptoms are often of long-standing duration, although it is not unusual to be asymptomatic as in 4 of our 17 cases.

Although dysphagia is the most common symptom, it does not appear related to size or location of the tumor. Hiatus hernias are frequently seen with leiomyoma, probably on the basis that such hernias are commonly encountered. According to Hodge,[11] the ratio of leiomyoma to hiatus hernia is 1:24.

When leiomyomata are associated with hiatus hernia, gastroesophageal reflux is frequently encountered. The cause and effect relationship between leiomyoma and hiatus hernia is unknown. It is speculative whether these tumors when present in the terminal esophagus interfere with functioning of the distal esophageal sphincter and result in gastroesophageal reflux. It would seem doubtful that reflux esophagitis from hiatus hernia would cause leiomyoma since they are extra-mucosal in location.

Documentation of the disease entity is accomplished by chest x-ray which often demonstrates a radio-opaque mediastinal density suggestive of tumor. This may be mistaken for a benign cyst. Contrast barium esophagrams are frequently performed and demonstrated a typical smooth crescent defect in the lumen. A circumferential leiomyoma may, however, be mistaken for a peptic stricture of esophageal ring.

Esophagoscopy should then be performed if there is any question of a malignancy. Since these tumors are extraluminal, normal mucosa is seen with a bulge in the region of the tumor. Biopsy of the mucosa is invariably normal. It is of interest that diverticula and carcinoma of the esophagus are rarely associated with leiomyoma. Hemorrhage from this tumor is infrequently encountered.

These tumors have a characteristic bosselated appearance. They are white, avascular, firm, smooth and not attached to surrounding structures, making them easy to enucleate.

Surgical treatment of this lesion is simple transthoracic enucleation of the tumor. Care is taken to split the muscularis and avoid perforating the mucosa. Entry into the esophageal lumen may be unavoidable where a previous biopsy has been taken via esophagoscopy.

In cases of unusually large tumors or densely adherent ones, esophageal resection may be necessary.[9] The rare predunculated tumor may be snared endoscopically. Repair of associated hiatal hernias seems warranted on the basis of the presence of the concommitant lesion and symptoms. In removal of large tumors of the distal esophagus, care should be exercised not to create a hiatus hernia.

Proper identification preoperatively by chest x-ray, barium swallow, esophagoscopy, intraoperative appearance, and a high index of suspicion make inadvertent esophageal resection for this condition unlikely. An increased awareness of this infrequent lesion will result in more precise preoperative diagnosis and improved surgical therapy.

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# Important Advances in Clinical Medicine

## Epitomes of Progress—Allergy

### Allergic Bronchopulmonary Aspergillosis

First described in 1952, allergic bronchopulmonary aspergillosis is being recognized with increasing frequency. The disease results from a hypersensitivity reaction to antigens derived from Aspergillus fungi which colonize the bronchial tree without tissue invasion.

The primary diagnostic criteria for this syndrome include (1) episodic bronchial obstruction (asthma), (2) peripheral blood eosinophilia, (3) immediate-type skin reactivity to Aspergillus antigens, (4) serum precipitating antibodies against Aspergillus antigens, (5) elevated serum IgE, (6) history of fixed or transient pulmonary infiltrates and (7) central bronchiectasis. Secondary diagnostic criteria include (1) the finding of Aspergillus in sputum or bronchial washings, (2) history of expectoration of brown plugs and (3) Arthus-type skin reactivity to Aspergillus antigens. Pathologically, allergic bronchopulmonary aspergillosis may show features of microgranulomatosis, muchoid impaction of bronchi, eosinophilic pneumonitis, bronchocentric granulomatosis or combinations thereof.

The disease should be considered in the differential diagnosis of any patient with asthma, eosinophilia and pulmonary infiltrates. There are no pathognomonic diagnostic criteria but the presence of the first six primary criteria determines the diagnosis with reasonable certainty. Proximal bronchiectasis tends to confirm the diagnosis although it may be absent early in the course of the disease.

In addition to morbidity from acute episodes, failure to make the diagnosis results in irreversible complications which include pulmonary fibrosis and bronchiectasis. The treatment for acute episodes and presumably for prevention of complications is administration of corticosteroids, though there are presently no established guidelines for optimal dosage or duration of therapy.

In addition to clinical findings, the serum IgE level may reflect disease activity, falling with appropriate treatment and rising before clinical relapse. As suggested by the immunologic findings in this disease, the immunopathogenesis probably involves both IgE-mediated or Arthus reaction and immune-complex mechanisms. The possible additional role of cell-mediated immunity remains to be clarified.

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### Primary Immunodeficiency in Adults

Although many of the syndromes associated with primary immunodeficient states were described in infants and children, it has become increasingly evident that immunodeficiencies not secondary to other diseases occur also in adults. Most of these patients have either a selective IgA deficiency ($< 0.05$ mg per ml of serum) or a more global deficiency. The latter are placed under the heading "common variable immunodeficiency," defined by a World Health Organization classification committee in 1971 as a heterogeneous group of disorders characterized by hypogammaglobulinemia and susceptibility to infections but variable with respect to age of onset, patterns of clinical manifestations and presence of cellular immune dysfunction. Although the immunoglobulins are produced by plasma cells derived from B (bursal equivalent) lymphocytes, most of the patients are not deficient in these cells. The defect appears to be in secretion of immunoglobulins. T suppressor cells, decreased T helper activity, a serum inhibitory factor and a missing serum factor have been detected in various patients.

The clinical presentation may be more similar than different in both groups. Sinopulmonary disease is common, a result of recurring infections with common pyogenic organisms leading to chronic sinusitis, recurring pneumonias and to peripheral bronchiectasis. Some patients develop a sprue-like illness and autoimmune diseases such as systemic lupus erythematosus and pernicious anemia. Food and drug reactions are relatively frequent.

Patients with common variable immunodeficiency usually have more serious pulmonary disease than those with only IgA deficiency, and they have a propensity for neoplasia. In one series, 16 percent developed malignancies, three fourths of which were of the epithelial type and the remaining lymphoreticular. Since many of these manifestations have in the past been considered evidence of immunological excess and treated with immunosuppressive agents, this viewpoint needs to be reassessed in light of the findings in primary immunodeficiency in adults.

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## Reactions to Food Additives

In 1959 Lockey reported the cases of three patients who developed urticaria from tartrazine yellow, and azo dye in their steroid medications. He noted that the same dye is used also for coloring foods, wool and silk. In the past 20 years additional reports have appeared implicating tartrazine yellow as a cause of urticaria, angioedema, asthma, or occasionally a violent systemic reaction. Although many of the reported cases have not been thoroughly documented, a large number of the tartrazine-reactive patients have a history of aspirin sensitivity and nasal polyps.

In 1969 Chaffee and Settipane reported the case of a patient with attacks of asthma and angioedema from the food preservative sodium benzoate, as well as from aspirin and tartrazine. Juhlin and co-workers did provocative oral challenges on eight patients with aspirin-sensitive asthma and found that seven reacted to tartrazine and two to sodium benzoate, and of 52 patients with chronic recurrent urticaria 35 developed hives after challenge with aspirin, 19 reacted to tartrazine and 22 to sodium benzoate. Other investigators have reported a considerably lower prevalence of reactors to these chemicals. Stenius and Lemola found that 25 of 140 asthmatic patients had a positive bronchoconstrictor response to challenge with tartrazine, although only 9 of these gave a history of aggravation of their asthma after ingestion of foods and drugs known to contain tartrazine, and another 7 patients with such a history gave a negative response to deliberate challenge.

Recently Freedman has added sulfur dioxide, a preservative used in orange drinks, to the list of additives causing asthma. This compound, which for years has been known to aggravate asthma when inhaled, caused bronchial constriction within two minutes when given by ingestion, and the effect was blocked by cromolyn sodium.

The mechanism by which these chemical additives cause asthma or urticaria is unknown. There is no evidence that immunologic hypersensitivity is involved, and because of the strong association with aspirin sensitivity it is probable that a nonimmunologic mechanism is involved in reactions to aspirin and the food additives. Several possible modes of pharmacologic idiosyncrasy have been proposed to account for aspirin-sensitive asthma. At present the prevailing theory of aspirin sensitivity is based on the known ability of aspirin to inhibit the biosynthesis of prostaglandins. Preferential inhibition of prostaglandin E synthesis in the lung, permitting the action of prostaglandin $F_{2\alpha}$, a potent bronchoconstrictor, to remain unopposed, would explain the asthmatic response. The mechanisim underlying urticaria and angioedema provoked by aspirin could be a different one, although the role of prostaglandins has not been excluded. In many patients with chronic urticaria, aspirin seems to act as a nonspecific potentiator. The results of experiments to study the effect of tartrazine, benzoates and sulfur dioxide on prostaglandin biosynthesis will be eagerly awaited.

Feingold has proposed that many unspecified food additives and "natural salicylates" may cause hyperactivity and learning disabilities in some children. This theory has gained popular support, but several recent controlled studies of his additive and salicylate-free diet have shown equivocal or no improvement in children with these disorders.

Food additives, numbering in the thousands, are widely employed to alter the color, taste, and texture of the food and to preserve freshness and inhibit contamination. It is therefore not surprising that some patients may exhibit idiosyncrasy or allergy to one or more of these substances.

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## The Use of Antihistamines in Bronchial Asthma

Antihistamines have been considered to provide either no benefit or even to be contraindicated in all asthmatic patients. However, recent studies have shown that these drugs do not necessarily cause a deterioration of the asthmatic state, and in fact may provide benefit. Antihistamines not only block $H_1$ receptors and thus partially block allergen induced bronchospasm, but they appear to have an anticholinergic effect as well. Popa has reported that high doses of chlorpheniramine given intravenously result in a significant degree of bronchodilation in asthmatic patients without atropine-like side effects. Furthermore, Karlin and co-workers have shown improved pulmonary function in patients with mild asthma receiving twice the usual recommended dosage. No adverse effects were seen in patients with chronic severe asthma receiving antihistamines for coexisting allergic rhinitis or urticaria.

These recent studies warrant the following conclusions:

- Asthmatic patients with allergic rhinitis may safely receive antihistamines in the usual dosage, and there is no evidence that coexisting asthma will be exacerbated.
- Although antihistamines can improve asthma in some cases, their use in asthmatic patients must be established on an individual basis.
- The use of antihistamines in patients with status asthmaticus cannot be recommended at this time because of the existence of more effective drugs and because potential drying effect of antihistamines on bronchial mucus has not been firmly clarified.

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## The Measurement of IgE

The American Academy of Allergy has appointed a Committee on Standardization of In Vitro Tests which is charged with defining and correcting the problems in the quantitation of IgE. They conducted a nationwide single-blind evaluation of the accuracy and reproducibility of the quantitation of IgE which showed an unacceptable level of variation. Besides the large variation between laboratories, the variation of repeated assays within laboratories was unacceptably large.

Part of the problem is undoubtedly due to differences in assay methods. A study of the various assay methods—radioimmunosorbent test (RIST), double-antibody radioimmunoassay (RIA), radial immunodiffusion (RID) and paper disc immunosorbent test (PRIST)—shows that RIST and RID may lead to spurious elevations of IgE in sera and secretions. Double-antibody RIA and PRIST provide the best agreement, but PRIST may give deceptively low results in certain sera. When all 14 laboratories assayed the test serum with the PRIST kit, variations within and between laboratories (133 units per ml to 330 units per ml) were still more than 2½ fold. The problems of the quantitation of IgE are being resolved and a "predictive" table of serum IgE levels in infants, children and adults, such as the one that follows, may be of value.

| *IgE—units per ml* | | | | |
|---|---|---|---|---|
| *Infants <2 yrs.* | *Children and Adults >3 yrs. (RIA)* | *(PRIST)* | *Percent of the Population* | *Allergic Percent* |
| <10 | <100 | <65 | 68 | <5 |
| 10-20 | 100-350 | 65-230 | 20 | 20 |
| 21-100 | 351-750 | 231-500 | 9 | 35 |
| >100 | >750 | >500 | <3 | ~100* |

*In the absence of helminthiasis.

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## Occupational Asthma

Occupational Asthma refers to a disease in those persons in whom asthma develops primarily from exposures at their work or hobby sites. Although occupational asthma dates at least to Ramazzini's reports in 1700 of asthma provoked by flour dust in bakers and wig makers, the sources of exposures seem to be on the increase in recent years. The provoking agents may be divided into those of (1) *animal origin* affecting poultry farmers; veterinarians; horse, cattle and sheep breeders; chicken inspectors; furriers, and aviarists; (2) *vegetable origin:* farmers, hempworkers, grainworkers, bakers, millers and woodworkers; (3) *inorganic chemicals:* chromium, platinum, aluminum and nickel factory workers, electricians, welders and solderers, and (4) *organic chemicals:* plastic makers and painters who handle isocyanates; meat wrappers exposed to polyvinyl fumes; workers in pharmaceutical plants, and workers using enzymes such as trypsin, Bacillus subtilis enzymes and papain. These are but a few examples of an almost endless list of occupations and causative agents in occupational asthma.

Asthma may occur not only in those who are predisposed by being atopic but also in apparently normal persons without a personal or family history of allergies or IgE specific antibodies. There is some evidence that the atopic persons have a more rapid onset of symptoms following exposures and tend to leave their jobs sooner. Asthma may occur within minutes of a sufficient exposure and responds well to bronchodilators. Others may have asthma delayed several hours after exposure and are better controlled by steroids than by epinephrine or theophylline. Some experience both immediate and late onset asthma.

The pathogenic mechanisms are not always clearcut. Some agents such as animal danders and enzymes are allergens producing specific IgE antibodies even in nonatopic persons. Others such as polyvinyl and acetylene fumes are respiratory irritants, while still others like toluene diisocyanate (TDI) may have both antigenic and irritant properties.

The examining physician can be alerted to the relationship of asthma to job or hobby by obtaining a careful history. A tip-off is the waxing and waning of symptoms, worse during workdays and better on holidays, weekends and vacations. Sometimes the exposure source may not be readily apparent, such as the case of a secretary whose office is clean but who shares access or ventilation with an adjoining factory. Confirmation that the suspected agent does provoke asthma may require bronchial challenge and immunological studies on the patient and control subjects. Discovery of occupationally induced asthma is rewarding, since removal from the exposure may well effect a cure.

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## Emergency Room Treatment of the Adult Asthmatic

During the course of chronic asthma, acute attacks occur that can be effectively treated in a hospital emergency room. A brief initial history can determine the possible precipitating cause of the attack, such as exposure to allergens or respiratory irritants, intercurrent viral respiratory infections, aspirin or other analgesics, emotional trauma, inadequate maintenance therapy, abrupt withdrawal of steroid medications, or overuse of aerosol bronchodilators.

Severe bronchial obstruction produces decreased breath sounds, notably prolonged expiration, use of accessory muscles of respiration and pulsus paradoxus. Tachycardia and mild hypertension are characteristic of acute asthma and not necessarily complications of treatment. Cyanosis, quiet chest, restlessness and exhaustion are ominous signs of impending or actual respiratory failure.

Arterial blood gas measurements are essential for determining optimal treatment. In uncomplicated mild to moderate asthma, hypoxemia secondary to ventilation-perfusion abnormalities stimulates hyperventilation resulting in a low arterial carbon dioxide pressure ($P_aCO_2$) and elevated pH. Normal or elevated $P_aCO_2$ indicates need for immediate admission to hospital. Pronounced carbon dioxide retention associated with signs of respiratory insufficiency may require immediate intubation and mechanical control of ventilation in a pulmonary intensive care unit.

If the patient has not already used sympathomimetic drugs excessively, injection of aqueous epinephrine 1:1,000, 0.2 to 0.5 ml given subcutaneously, should lead to rapid improvement, and this dose can be repeated in 30 minutes if necessary. Terbutaline, 0.5 ml given subcutaneously, is theoretically less cardiotoxic, although its superiority over epinephrine in the emergency room treatment of asthma has not yet been established.

Intravenously given aminophyllin should also be used immediately. If no aminophyllin had been taken in the preceding eight hours, an initial loading dose of 5.6 mg per kg of body weight can be given over 20 minutes, followed by an infusion of 0.9 mg per kg of body weight per hour to achieve a therapeutic serum theophyllin level of 10 to 20 mg per liter. This dose must be lowered if the patient had been taking aminophyllin orally or has evidence of cardiac or hepatic disease.

The need for corticosteroids must be judged on an individual basis. Intravenously given hydrocortisone or methylprednisolone is mandatory if respiratory insufficiency is present or if the attack was caused by abrupt withdrawal of previous steroids or bronchodilator aerosol abuse. Nasal oxygen is given to correct hypoxemia, and blood gas determinations are repeated in 20 to 30 minutes and thereafter as indicated by the clinical improvement. There is no indication that asthmatic attacks are caused by bacterial respiratory infections, or that antibiotics are useful in the acute attack.

The effect of treatment can be assessed by repeated auscultation of the chest, but a simple test of ventilation, such as peak expiratory flow rate (PEFR) as determined by a Wright Peak Flow Meter, can be very helpful. Banner and co-workers recently showed that failure to improve PEFR by 15 percent immediately and 42 percent at the end of emergency room treatment probably indicates the need for admission to hospital.

Administration of sympathomimetic drugs by intermittent positive pressure breathing (IPPB) in acute asthma is controversial, and the dangers are significant. Karetsky recently reported the cases of two patients who died from subcutaneous emphysema and pneumothorax during the course of such treatment for acute asthma.

At the conclusion of the emergency room visit, arrangements should be made for follow-up management to prevent recurrences. It has been well documented that small airway obstruction can persist for days and weeks after clinical signs of the acute attack have cleared completely. Regular continuing outpatient management of asthmatic patients significantly reduces the need for emergency room visits.

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## Medicine and Technology

Doctors' professional values are largely formed in medical school, of course, and it is there that any basic change in orientation should naturally begin. At Harvard Medical School, for the past two years, a rebellion of sorts has been under way, in the form of a semester's course titled "Social Theory, Human Values, and the Healing Relationship." Taught by Jerry Avorn, himself a Harvard Medical School graduate, the course has been offered to second-year students as an elective, in conjunction with the required "Introduction to Clinical Medicine." Next year it will be incorporated as part of the requirement.

Dr. Avorn, who good-humoredly refers to the medical "counter-revolution" of which he is a part, believes that doctor-patient rapport "began to decline with effective tests and medicines. The attitude developed, 'If the drug works, it works,' The doctor's personality didn't matter much." He feels that unquestioning faith in drugs met its severest test with the thalidomide tragedy of the early Sixties, which he terms "the Three Mile Island of pharmaceuticals." The comparison of medicine to nuclear power is not accidental. "Medicine is a highly developed profession, technologically," Dr. Avorn says. "But people are starting to realize that it is not omnipotent, that the cure-all promises won't happen. There was a 'high' period during World War II and afterwards." He also notes that the nature of the illnesses doctors treat today is changing. "There are more chronic, incurable diseases, where the importance of the doctor-patient relationship is re-emphasized. Also, patients are intimidated by doctors because they are lower on the social ladder compared to them than before. The old M.D. was like a traveling salesman; today he has too much status to be bothered with that." Dr. Avorn steers a moderate course, taking advantage of technology, but he emphasizes to his students the need to use all available techniques—compassion and understanding included.

"The Healing Relationship" weaves practice into theory, its lectures and reading supplemented by class discussions and clinical encounters. Even the reading list departs from standard medical texts to include works by Tolstoy and Shaw. Students study how to listen to patients; to understand the special needs of the elderly; to confront dying patients and the impact their death has upon the physician and the family; power conflicts among doctors and the initiation of doctors-to-be into the medical "guild." They watch videotapes Dr. Avorn has made of his own patients at Boston's Beth Israel Hospital and conduct similar interviews in class. In papers based on their own clinical experiences, they verbalize not only the patients' feelings but their own. "It's best to reach students when their minds are most open about these issues," Dr. Avorn says, "when they haven't been socialized as doctors, and are still willing to admit there's more to medicine than ordering the right lab tests."

—*Harvard Magazine,* July-August 1979

# CSMS—AEtna Professional Liability Program

Semi-Annual Activity Report

FRANCIS P. GINTY

## I. EXPERIENCE

For purposes of continuity of data analysis, the format of prior reports is retained. Exhibit A reflects loss activity through the second quarter of the 8th Account Year. Six months ago we reported a number of arising claims or suits was *1,207*, an increase of 14% over the prior six month period. At present, there have been *1,321* claims made—an increase of 114 cases, or *9.4%* in the last six months. In the short term, the number of arising claims continues at a decreasing rate, but not as great as in the prior two six month periods. One year ago, arising claims were down by 28%: six months ago by 14%. During the same time periods, open and outstanding cases increased by 16%. In the last six months the number of open cases* increased from 434 to 441, an increase of only *1.6%*.

This is a desirable trend in the reduction of outstanding cases. Open cases lend themselves to increased dollar values due to inflation and unfavorable changes in the legal climate. Aggressive claim handling accounts for the check on a highly undesirable trend seen in the previous year.

Exhibit A
LOSS ACTIVITY

| *Account Year* | *Incurred Losses* | *Arising Claims* | *Open Claims* |
|---|---|---|---|
| 1971 | $ 1,354,233 | 111 | 14 |
| 1972 | 2,881,875 | 207 | 38 |
| 1973 | 2,340,083 | 220 | 63 |
| 1974 | 3,244,040 | 264 | 91 |
| 1975 | 5,938,157 | 255 | 115 |
| 1976 | 2,748,301 | 185 | 89 |
| 1977 | 858,300 | 64 | 22 |
| 1978 (6 mos.) | 232,783 | 15 | 9 |
| TOTAL | $19,597,772 | 1,321 | 441 |

*"Open cases" are still in the process of settlement, litigation, and/or other disposition.

The *unloaded* loss experience** increased by $4,440,755 or *29.2%*, 4½ points higher than the previous six month period. In both periods, incurred losses increased double the rate for the prior Account Years. The last year reflects increased losses of 8.7 million dollars, *almost double* that of the prior seven Account Years. In the last 24 months, the average cost per claim (severity) has increased from $8,993 to $10,154 to $12,550 to a present average cost of $14,836. Prior Account Years developed increases of $1100 per claim. At present, severity is increasing double that amount in the same time frames. This data confirms that a severity rate of this magnitude was not anticipated in the actuarial trend factors reflected in the 1977-1978 Account Year Annual Report. That year produced a return of almost three million dollars to the Society membership as a dividend.

The Company is justifiably concerned, and the Society should be, by the serious deterioration of program results, noted in the last year.

## II. INCIDENT REPORTING

In the past Account Years this report reflected the tracking of incidents intended to monitor the specialties of medicine which produced the most claim activity. The volume of claim data available in the CSMS program easily identifies the specialties of anesthesia, obstetrics, general surgery and orthopedics as producing not only the largest number of claims, but more significantly, the greatest exposure in terms of dollars paid and reserved by AEtna's Claim Department. National data is consistent with claim activity in Connecticut.

A recent analysis of claims reported reflects that, despite our emphasis, *physicians still delay in reporting incidents which occur and have potential*

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MR. FRANCIS P. GINTY, Aetna Administrator for the CSMS Professional Liability Program, now in its seventh year of existence. *This report was issued to the CSMS Committee on Professional Liability in May, 1979.*

**Unloaded loss includes both closed, paid claims, and reported open claims for which reserves have been set aside at currently estimated value. It does *not* include actuarial loading factors for claims incurred but not yet reported (IBNR), future loss development and inflation, or future loss adjustment expense (legal fees and costs).

Exhibit B

"THE LONG TAIL": CLAIMS REPORTED BY 4/79

| *Account Year* | *1972* | | *1973* | | *1974* | | *1975* | | *1976* | | *1977* | | *1978* | | *1979* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 4/72 | 10/72 | 4/73 | 10/73 | 4/74 | 10/74 | 4/75 | 10/75 | 4/76 | 10/76 | 4/77 | 10/77 | 4/78 | 10/78 | 4/79 |
| 10-1-71/72 | 7 | 35 | 54 | 67 | 78 | 93 | 101 | 103 | 108 | 106 | 107 | 106 | 108 | 111 | 111 |
| 10-1-72/73 | | | 16 | 54 | 100 | 123 | 153 | 182 | 191 | 198 | 199 | 204 | 206 | 207 | 207 |
| 10-1-73/74 | | | | | 19 | 49 | 82 | 111 | 160 | 198 | 209 | 217 | 220 | 220 | 220 |
| 10-1-74/75 | | | | | | | 25 | 76 | 133 | 158 | 198 | 241 | 255 | 262 | 264 |
| 10-1-75/76 | | | | | | | | | 12 | 55 | 166 | 139 | 182 | 257 | 255 |
| 10-1-76/77 | | | | | | | | | | | 22 | 56 | 94 | 129 | 185 |
| 10-1-77/78 | | | | | | | | | | | | | 10 | 41 | 64 |
| 10-1-78/79 | | | | | | | | | | | | | | | 15 |
| TOTAL ARISING CLAIMS | | | | | | | | 472 | 604 | 755 | 841 | 963 | 1075 | 1207 | 1321 |

*for a claim.* This represents a time lag, too long for effective action to reduce the cost of claims. The average reporting time to the company in Connecticut is 14 months—long enough to increase the cost of the claim by as much as 50%. While this delay is shorter than the national average, the effect is frustrating in terms of early investigation and evaluation when appropriate action by AEtna in the disposition of claims. Why program physicians have reverted to the early practice of delayed reporting is puzzling, since the character of many claims presently made indicates a problem was apparent at the time of the mishap.

This delay only benefits patient's counsel, who perfect their case while AEtna waits unaware and unable to prepare a proper defense. The attendant increased cost will be borne by the entire membership.

A review of Exhibit B reflects not only the desirable moderating trend of claims, but the effect of the "long tail"† demonstrated by delayed reporting of incidents by six month periods in each Account Year. In the early years of the program, with less than half the participating membership, reporting within six months was as good and got better until this last year. Earlier predictions by the Account Supervisor were that the mature Account Years would produce an average of 250 claims. This became fact in the middle Account Years and will continue, unless frequency of claims begins to decline at a greater rate.

In the months which follow the Society and AEtna will endeavor to convince the membership that *early reporting will not only avoid law suits* but will provide AEtna the opportunity to dispose of meritorious claims for fewer dollars. Early reporting is not reflected in increased premium. In fact, the opposite is true.

AEtna's experience has been that most physicians respond favorably to an honest opinion from AEtna's Claim Department, counsel provided, or especially to a vote of their peers in a review of the case before a defense panel—particularly the determination of fault. They do try to assist in determining whether there has been actual negligence and if so, what party to the event should accept responsibility for the patient injury. In most cases an early discussion with all parties including frank and open assessment of the facts surrounding the incident, can assist in a determination of a cause of action which may obviate the need to involve the physician in protracted litigation. This makes early reporting a logical step. The motivation to do otherwise is misguided.

## III. CLAIM CLIMATE

Previous reports to the Society have suggested that emphasis on injury and not obvious negligence is the present motivation for malpractice litigation. Unquestionably, both are present in many of the newly arising losses. "Injury makes the liability" is a legal axiom not to be considered frivolous by physicians. There is hardly a record or chart which comes before a peer review panel of the Society, which, in hindsight (the view from the jury box), escapes criticism. Yet the trial of a malpractice case in the hands of skilled plaintiff's counsel encompasses both educational and persuasive elements for the jury to consider. Unless juries are informed, they are generally reluctant to find fault. Once enlightened, however, their role becomes the responsibility to establish medical standards to be applied for the benefit of the entire community of medical consumers.

Continued review of the allegations of negligence cited in law suits brought continues to reflect the emphasis on *injury,* with or without attendant liability. These suits are consistent with the motivation of patient's counsel as discussed above. Injury is the criterion for most of the newly arising law suits.

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†"The long tail" is the extended period of time after an account year in which claims are reported and litigation is pursued before a final accounting can be made of the actual losses for that account year. For example, two more cases were reported for the first time which occurred during the 1971 account year. In addition, fifteen of the 1971 cases are still in litigation, and it remains to be seen whether adequate funds have been reserved to cover the eventual outcomes of these suits. The earliest possible reporting by insured physicians themselves of potential malpractice claims is vital not only to alleviate the adverse effect of the long tail on insurance rates, but also to preparing an effective and successful defense or settlement.

In May, 1978, we reported 395 suits were pending; in November, 1978, there was a decrease to 383. At present, *431* suits are pending, an increase of *12.5%*. Since the number of arising suits are increasing at a somewhat higher percentage than claims made (but not in suit), there suggests further evidence that the problem of delayed reporting is on the increase.

Like old wine, old law suits cost more.

In the cases which come before us now, the best of counsel for the patient gear toward trial and not settlement. This is the most important significant change in malpractice litigation. It has been said that only the loss of a malpractice suit will raise the standards of practice.

This argument may have some merit. A jury which becomes incensed at a doctor's incompetence or indifference in his treatment of a patient, becomes receptive to the argument he has failed in his responsibilities as a doctor. These perceptions become considerations, aside from the failure to meet the standard of care, in the assessment of the ability to perfect a defense of a malpractice case. The issues have become more complex.

Defense counsel and the AEtna Claim Department have been put in the position of having to explain why or how a patient was injured or disabled without the negligence of the doctor. Contrary to law on the burden of proof, this is a fact of life in the present claim climate. The defense is truly on the defensive. We are forced to attack, refute, disprove or mitigate the picture painted by the patient, in the face of horrendous injury. There is little likelihood this responsibility will abate in the foreseeable future.

The next section deals with the most effective tool the Society's program provides for the early evaluation of exposure based on the medical facts, i.e., peer review.

## IV. CLAIM DEFENSE PANELS

As such, the peer review mechanism represents the closest association of AEtna and CSMS on Loss Control and Education. Organization and implementation, through the cooperation of the Chairmen of the four panels, counsel to physicians and CSMS staff, have made possible the review of approximately *300* cases, using the expertise of over *700* physicians within the program. As such, it is generally agreed among counsel and physicians as the best forum ever available for evaluation and equitable disposition of cases, as well as for education.

The formal review of cases by and for physicians became a regular activity of the Society in 1975. Since that time, it has become the object of assessment by other state medical societies, outside AEtna programs and even HEW. Visitors have attended the sessions, coming away with a certainty of their effectiveness—due primarily to the depth of analysis of the problem presented, as well as the objectivity of the panel members and guests and their assessment of the medical management of cases presented. The extent to which credibility is attributed to the panel mechanism is attested by the fact that not a single defendant has refused to appear before a panel. More importantly, the AEtna has responded to the medical issues adjudicated by disposition of cases almost proportionate to the votes taken.

The Claim Defense Panels remain the most important component of the Loss Control and Education Program, due primarily to this credibility. They have the full and continued support of the Society membership, counsel to defendant doctors, and the AEtna Claim Department.

## V. LOSS CONTROL & EDUCATION

Well before the "malpractice crisis" began to develop in 1975, the AEtna viewed its partnership with CSMS (beginning in 1971) as an opportunity to reach physicians with a program of education designed to focus attention on the causes and prevention of malpractice suits. It drew on its own experience which clearly delineated deviation from the basic standards of care as the cause. Education programs were built around a return to the basics of good record keeping, patient rapport, etc.

Cynics viewed our approach as simplistic; our program materials and aids as less than sophisticated, and worse, our efforts feeble and ineffectual. We disagreed then and do now. If our detractors are correct, it is an irony that many insurance carriers have adopted the CSMS/AEtna approach over the last few years. Outside consulting firms have made much money borrowing from our conceptual approach, and the government has lauded AEtna for its pioneer efforts to respond effectively and appropriately to an obvious need.

Much agitated discussion has arisen in the past four years regarding medical malpractice questions. Medical societies, hospital associations, bar associations, insurance representatives and legislators, (both state and federal) have debated one another with far more heat than light. Numerous solutions have been proposed, but none thus far has proved ideal. Some have already demonstrated clear weaknesses, but few have had time enough for a fair appraisal. The Account Supervisor has been privy to most of the alternatives presented. Nevertheless, the government (HEW) has seen fit to mandate risk management for hospitals. Presented the opportunity, government would impose similar constraints on physicians. This need not be—considering the effort extended and cooperation afforded by the Society in adopting action well before its time. The AEtna intends to continue to advance and expand the present loss control program. A new dimension, however, is presently in its formative stage.

Recognizing the malpractice controversy has an indirect and undesirable effect on the quality of care, we and the Society have nevertheless agreed the threat of litigation provides a motivator to change physician behavior. We have agreed the time has come for *physicians* to decide what physicians should do to avoid patient injury. The present state of the law in Connecticut suggests clearly that the major cause for malpractice liability is incompetence or negligence.

The profession of medicine has not been convincing in advancing reasons for its own inability to undertake adequate self policing and internal disciplinary action. The juries (as suggested above) are reacting to this perceived apathy.

In an effort to do something positive to effect the needed changes in the behavior, the AEtna and the Society have tentatively agreed that loss control must become an exercise by and for physicians. A program to be financed by AEtna will shortly be introduced to the Society by a select ad hoc committee, chosen by the Chairman of the Professional Liability Committee. Their charge is to develop programs (by physicians) which address a single aspect of the malpractice problem—medical care—the importance of which should not be obscured by the current preoccupation with the economic and insurance factors. In short, the Society will attempt to concentrate on the scientific basis of the problems and their potential clinical or educational resolution, apart from legal defenses and insurance considerations.

The discussion to date with this committee suggests an answer may lie in fostering funded programs for research and analysis, aimed at increasing knowledge and understanding of patient's psychological and psychosocial needs, as well as identification of violations of scientific principle or deviation from accepted management of patient care. The findings of such research should be translated into specific action programs aimed at improving the methods of management of health care and at improving the approach of physicians in the human as well as medical aspects of patient care.

It frequently does take a "crisis" or the appearance of one to galvanize action. Present loss experience in the CSMS program is identified presently as such a crisis. We are convinced that there is a willingness of the medical profession to acknowledge and face up to unnecessary shortcomings in the quality of care and in the doctor-patient relationship. The physician-designed loss control program now being formulated by CSMS promises to be an exciting adjunct to the total program sponsored and implemented by AEtna alone in past years.

More factual information will be available at a later date when the committee submits formal recommendations for implementation of this innovative and unique approach to loss control.

## VI. LEGISLATIVE ACTIVITY

The laws that control malpractice litigation have developed through two distinct methods: Statutory provisions and the common law.

The common law is a body of rules and principles, written and unwritten, which are of fixed and immutable authority, applied to malpractice. Presumably, they could not be modified to suit the peculiarities of specific cases or colored by any judicial discretion. And yet they have been. Recent court decisions imply that physicians have long enjoyed a privileged status under the law. This is not the case at present; nor likely to be in the future.

Neither the Society nor AEtna viewed tort reform as the ultimate solution to the problem. Modification of the present system was expected to be met by resistance. In the past few years our combined efforts were reasonably well received and certain legislation (described in detail in earlier reports) was viewed as a step forward to protect physicians. Today's legislative climate in Connecticut appears to preclude any attempt to change the law—such proposed legislation seeming to benefit a privileged class, and lacking support from the legislators and their constituencies.

The most important piece of legislation directly affecting Connecticut physicians is the regulation on Informed Consent, adopted by the legislature as finally submitted by the Department of Public Health. Any suggestion that this regulation is not binding on every physician in the state is misguided. Its provisions should have become the common knowledge of physicians; and yet it is feared they will continue to be ignored, perhaps providing, for the first time in Connecticut an allegation of negligence entirely predisposed for recovery by the plaintiff in an action based upon this single allegation.

## VII. CONCLUSION

As long as the common law tort system continues to recognize a legal cause of action for medical malpractice, physicians are going to be faced with the problems associated with malpractice. The hope of some to eliminate this cause of action, will receive no appreciable acceptance by lawyers, legislators, or the health care consumer. Such a solution may be exceedingly offensive because of its apparent effect of protecting only the interests of the "compact minority" of providers. The trend is toward assisting consumers in the exercise of their legal rights, rather than prohibiting them. As a result, the most viable solutions to the malpractice crisis then become those financially underwriting the risk and those reducing the risk.

The goals and objectives of the Society and the AEtna alluded to above are suggested approaches to implement effective and efficient injury protection programs. Such programs suggest the possibility of linkage between CSMS and utilization of extant standards review programs, the voluntary efforts of the JCAH, but more importantly the CME programs, as well as other appropriate programs, which are ultimately aimed at the reduction of patient injuries.

Discussions with the Professional Liability Committee and its ad hoc committee on the prevention of patient injury, suggests the desire to reduce the cost of malpractice is shared by more of today's providers than previously was the case.

The ways and means of accomplishing this goal will become, we hope, the subject of much future managerial time and effort. The medical liability problem has not been solved and most doctors know it. Attitudes have changed but not enough; nor are such changes substantial enough to describe the situation as chronic rather than acute. Our efforts in the months ahead will be directed to get the malpractice problem off dead center and to move toward new solutions.

If such efforts are successful, the incidence of malpractice may decrease. In the final analysis, it is the reduction of patient injuries that should be most important to the physician, the public, and the insurance carriers.

## Professional Liability and Discipline

Much accomplished since "crisis" of 1974 via *state tort reform* and availability of liability insurance. Insurance generally available; 20 medical society-created/physician-owned insurance companies cover 78,000 physicians. Premium increases have leveled off; some companies *decreased* rates in 1977.

In 1976 AMA activated American Medical Assurance Co. to *improve reinsurance* opportunities for approved MD/medical society companies. AMACO provides portion of reinsurance for 10 companies covering more than 40,000 physicians.

AMA developed model laws. More than 300 separate laws passed by 50 state legislatures including 1) risk pools; 2) tightened statutes of limitations, and 3) informed consent changes. AMA continues to urge state, not federal, legislative action.

Disciplinary action against MDS up 6-fold between 1971-1977.

In 1971 there were 119 actions which revoked licenses, suspended narcotic permits, censured MDs or denied licensure; in 1977 there were 685 such actions. Much of increase attributable to rising number of states providing immunity from civil liability for persons making reports to state disciplinary boards.

Fifteen states enacted all or part of AMA model legislation proposal designed to create broad range of flexible disciplinary actions and help licensing boards be more effective.

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## HISTORY OF MEDICINE

# Laetrile in Historical Perspective

JAMES HARVEY YOUNG, PH.D.

Laetrile's history has been complex, tortuous, kaleidoscopic, too complex for adequate summary in twenty minutes. A longer documented version of this paper has been prepared for publication. Beginning inauspiciously, Laetrile soared to a notorious pinnacle as the unorthodox brand-name health promotion generating the greatest public furor in the nation's history. In Laetrile's history three successive periods may be designated: the creation by the Krebs, the McNaughton ascendancy, the appeal to freedom.

Two men, each named Ernst T. Krebs, father and son, brought Laetrile to market and dominated its early years. The father, a physician, had, in the 1920s, put out a proprietary version of a wild parsley which, he declared, had protected Nevada Indians during the influenza pandemic of 1918. Despite seizures under food and drug law, this early antibiotic—as Krebs later considered it—was still sold in the late 1950s under the guise of an investigational prescription drug. While practicing medicine in San Francisco, Dr. Krebs released other new therapeutic entities, including an enzyme to treat cancer and an apricot kernel extract termed "a systemic detoxicant" for treating allergies.

Dr. Krebs told two tales about Laetrile's origin. The later account traced its history back to the 1920s. This version appeared when a long history for Laetrile might prove legally important, because "grandfather" clauses in food and drug laws permitted old drugs to escape some aspects of regulation. The earlier tale dated Laetrile's birth to 1951. In 1952 Dr. Krebs told Food and Drug Administration inspectors that the previous year he had begun experimenting with a cyanogenetic glucoside extracted from apricot pits. This extract, Krebs said, liquefied malignant growths when injected near them. His son had somewhat refined the product and named it Laetrile.

Ernst Krebs, Jr., had spent three years at Hahnemann Medical College without graduating, had received a bachelor of arts degree from the University of Illinois, and had studied anatomy for two years in the University of California graduate school at Berkeley before being dismissed for pursuing what was deemed unorthodoxy. Shortly after Laetrile was named, the Krebs sought to explain its purported efficacy in treating cancer by means of a trophoblastic or unitarian hypothesis. This theory, borrowed from a turn-of-the-century Edinburgh embryologist, held that cancer was caused when that primitive cell, the trophoblast, went astray. Laetrile, when injected, the Krebs asserted, reached the cancer site and there, hydrolyzed by an enzyme more abundant in cancer than in healthy cells, released cancer-killing hydrogen cyanide. Normal cells were protected by another enzyme which detoxified cyanide, an enzyme cancer cells lacked.

With Krebs, Jr., as managerial "guiding light," a number of intertwining organizations were set up to produce and distribute Laetrile. Krebs showed his merchandising zeal in a letter to an entrepreneur hoping to market Laetrile abroad: " . . . [T]he field of *cancer chemotherapy* is a law to itself. This jungle offers the greatest opportunity anywhere in commerce at the moment, but there are snakes in every bush. . . . [P]ush hard, sell, don't be backward about disaffecting a few, and establish . . . [Laetrile] right from the start as something precious that not even hospitals get for nothing."

A few physicians in the United States and overseas began to use Laetrile in treating cancer patients. Efforts to get publicity alerted the Cancer Commission of the California Medical Association which in 1953 issued a critical report. Tests with mice showed

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*This is a shortened version, read at the annual meeting of the American Association for the Advancement of Science, Houston, January 6, 1979, of a chapter by the same title which will appear in Gerald E. Markle and James C. Petersen (eds.),* Politics, Science and Cancer: The Laetrile Phenomenon, *Westview Press, forthcoming.*

that Laetrile did not have any effect on the course of cancer. Nor did a study of the records of forty-four patients reveal objective evidence that Laetrile alone exercised any control over cancer. Nor did the trophoblastic theory conform to biochemical facts. This was the first of numerous similar critiques from cancer specialists to be issued in the years ahead. The Food and Drug Administration kept Laetrile under close scrutiny but did not take immediate regulatory action. " . . . [T]his type of promotion," a headquarters memorandum read, "namely an article distributed as a new drug for investigational purposes but indirectly promoted for use in cancer, is hard to handle." In 1960 the FDA made its first seizure of a Laetrile shipment, one directed to Harry Hoxsey's moribund cancer clinic in Dallas.

The first period of Laetrile's history, during which the Krebs' brand of amygdalin, shrewdly but cautiously promoted, made modest gains without encountering serious regulatory trouble, ended about 1963. By then both state and federal governments had attacked in force, in an atmosphere of public worry about drugs cued by thalidomide. So besieged, the Krebs yielded real control to an international adventurer possessing capital, audacity, and a broader vision of Laetrile's destiny.

Andrew R.L. McNaughton, son of the head of Canada's armed forces during World War II, had himself enjoyed a glamorous if checkered career as test pilot, gun runner, and stock promoter. In 1960 he took Laetrile from San Francisco to Quebec, distributing it through his private McNaughton Foundation to physicians as an investigational drug. The next year he set up a plant to manufacture and distribute it. In the United States McNaughton took Krebs, Jr., with him to Washington, hoping to persuade regulatory officials to consider favorably a New Drug Application, without success. McNaughton also increased the drumbeat of publicity. In 1963 an author who earlier had acclaimed Krebs, Jr., Nobel Prize material published a paperback book proclaiming that Laetrile would "be to cancer what insulin is to diabetes." Two chapters were prepublished in Hearst's *American Weekly*. In the book's foreword, McNaughton solicited inquiries addressed to his Foundation.

Public interest, especially among desperate cancer sufferers and their families, thus was stimulated at the same time that the national governments of the United States and Canada and the state of California launched legal actions to suppress Laetrile as a drug whose sponsors had not undertaken their lawful obligation to demonstrate its safety and efficacy. Both Dr. Krebs and his son, as well as physicians prescribing Laetrile, suffered legal restraints. Canadian action forced McNaughton to shift his base of operations to California where he took over leadership of the enterprise from the Krebs.

McNaughton's efforts in 1970 to get an Investigational New Drug application approved for Laetrile became a *cause célèbre*. Handled by the Food and Drug Administration according to then prevailing practice and rejected because of inadequate data, the IND episode became converted by Laetrile supporters into a tale of FDA's perfidy. That a broader network of health unorthodoxy had come to champion Laetrile may be seen by the way in which such organs as the National Health Federation's *Bulletin* and the magazine *Prevention* rebuked the FDA. In this crisis a new Laetrile spokesman emerged, a recruit from the ranks of orthodoxy, Dr. Dean Burk, who had devoted more than forty years to cancer investigation and then served as chief of the Cytochemistry Section of the National Cancer Institute. A new organization also bolstered Laetrile's cause. A San Diego schoolteacher, Cecile Pollack Hoffman, although she later died of cancer, credited with curing her the Laetrile given her first in Quebec and then in Tijuana as the first Laetrile patient of Dr. Ernesto Contreras. In 1963 she created the International Association of Cancer Victims and Friends to promote Laetrile. "Freedom of choice" became her battle cry.

As the intensity of pro-Laetrile propaganda increased, more physicians sought to secure and prescribe it, at the same time that regulatory pressure mounted. Before his death in 1970, Dr. Krebs had been enjoined by federal action and later cited for criminal contempt. Krebs, Jr., pleaded guilty to a California action aimed at his distribution of a prohibited drug, and that state sought to stop an "underground railroad" operation which assembled cancer victims from all over the nation in boarding houses on the border, then ran them across to Tijuana for Laetrile treatments at Dr. Contreras' booming operation. McNaughton financed a new clinic for Contreras and, because of the American regulatory climate, moved manufacturing machinery and operations from San Francisco to Tijuana.

Regulatory pressures helped speed other changes, some already launched, that remade Laetrile's self-image, the explanation for its purported therapeutic action, indications for its use, the strategy and tactics of its promotion, even its very name. In the third period, while McNaughton continued, as a reporter put it, "more than any other man . . . the driving force behind the [Laetrile] movement," he gained powerful allies in the United States. The arrest in 1972 of a California general practitioner, Dr. John Richardson, for prescribing Laetrile, upset his fellow members of the John Birch Society who saw in his plight a prime example of bureaucratic oppression. Led by Robert W. Bradford, a nuclear technician at Stanford, a small group of ultraconservatives founded the Committee for Freedom of Choice in Cancer Therapy. Within five years the Committee had grown to some 500 chapters with 35,000 members. Stressing high Constitutional principle, terming Laetrile's opponents a selfish conspiracy of orthodox cancer workers fearful of losing their jobs, blasting orthodox therapy as hazardously futile "cutting, burning, and poisoning," the Committee showed great ingenuity at making their message known. They used meetings, films, pamphlets, paperback books, a magazine, quickly triggered letter-writing campaigns.

The Laetrile now being promoted had changed from a chemotherapeutic agent to a vitamin, so-called Vitamin B-17, and in the transition cancer had become a deficiency disease. This permitted preventive as well as therapeutic dosage, made easier by the advent of oral dosage forms to supplement injections. McNaughton's plant marketed such tablets devoid of labeling references to cancer, presumably trusting the publicity about Laetrile to make the message clear. If every American took Laetrile regularly, Dr. Richardson told a Senate subcommittee, "in 20 years cancer would be relegated to the dusty pages of history."

The Food and Drug Administration brought legal actions against Bee-Seventeen and other oral forms. And the government initiated a major action against many leading Laetrile figures, including McNaughton, Dr. Richardson, and Bradford, charging a conspiracy to smuggle Laetrile into the United States from Mexico and to distribute it throughout the nation, alleging huge profits from this operation. Convictions secured were confirmed in October by the Court of Appeals for the Ninth Circuit.

Laetrile's defenders launched a counter-offensive, both in the courtroom and in legislative halls. Key case in the judicial campaign centered on a Kansas salesman, Glen L. Rutherford, who, treated for cancer at Contreras' clinic, won from a federal district court in Oklahoma a class action suit permitting him and other victims of cancer, designated terminal by physician affidavit, to import maintenance injections and tablets of Laetrile. The Court of Appeals for the Tenth Circuit ordered a fuller administrative record from the Food and Drug Administration.

Assessing 400 written statements and testimony from two days of public hearings, the FDA issued a report. In it Commissioner Donald Kennedy countered claims made for Laetrile's effectiveness in cancer, disputing the shifting theories (including the vitamin stance), remarking the inadequate anecdotal character of pro-Laetrile case reporting, and citing the lack of promise in the numerous animal studies made by the National Cancer Institute and private cancer research centers. The few animal tests interpreted as favorable by Laetrile supporters the FDA directly criticized. The "disparagement of conventional therapy," the Commissioner stated, " . . . is perhaps the most morally reprehensible aspect of the pattern of . . . [Laetrile's] promotion." The report also met the "freedom of choice" argument head on, noting that Congress had barred free access to ineffective drugs in exchange for freedom from the danger posed by worthless drugs. In any case, the choice of Laetrile, made in an atmosphere of double stress, compounded from fear of cancer and from the pressure of Laetrile advocates, could seldom be accurately described as free.

The Oklahoma judge, however, was not persuaded. He maintained his injunction in force. On appeal, the Tenth Circuit, in July 1978, ruled that the law's taboo against the marketing of drugs not proved safe and effective by their sponsors did not apply to drugs prescribed for people who were dying. Patients whose physicians would certify that they were terminally ill with cancer could legally import Laetrile—but only for injections, not in oral form. The Court had been impressed with mounting evidence of amygdalin's danger when taken by mouth. In contrast with the Tenth Circuit, some other federal courts, including the Seventh Circuit, upheld the FDA's interpretation of the law, a conflict that the Supreme Court will in due course adjudicate. In the meantime, the affidavit system itself has become a cloak for fraudulent imports.

Laetrile's champions also took their case before state legislatures. The freedom of choice argument impressed some assemblymen upset for their own reasons by the considerable federal presence. Beginning with Alaska in September 1976, seventeen states over the next two years enacted pro-Laetrile laws with varying provisions, amidst much national publicity. Other states considered but defeated Laetrile bills, and bills fared less well in 1978 than in 1977. Still, some kind of approval from seventeen states enhanced Laetrile's prestige. To the ordinary citizen, sanction might equate with efficacy.

The prominence of Laetrile as a political issue and a media topic, and its considerable use, perhaps by 75,000 Americans, provoked the argument that, even if its promoters would not assume their legal obligation, Laetrile ought to be tested in well controlled clinical trials, if only to reveal its ineffectiveness. This possible course caused, and still causes, sharp debate within the scientific community. The National Cancer Institute made a retrospective study confined to the records of patients whose physicians thought they had benefited objectively from the use of Laetrile. Despite a vast publicity campaign, only twenty-two cases were submitted on patients treated with Laetrile alone for whom records seemed adequate for appraisal. While granting that data might have been improperly interpreted or even falsified, a panel of reviewers read the records as apparently suggesting that seven of the twenty-two patients had worsened, nine had remained the same, and six had responded favorably. The National Cancer Institute in September 1978 announced its decision to seek from the FDA an IND to undertake a clinical trial of amygdalin with terminal cancer patients. In December the NCI made formal application. The NCI director hoped the outcome would resolve the debate over Laetrile "once and for all."

Such optimism seems unwarranted. From the beginning, as a basic premise, Laetrile's supporters have questioned the validity of experiments conducted by experimenters who do not share faith in the theories supporting Laetrile's value. Unless an NCI study should be conducted "in the way that the proponents of Laetrile . . . are urging that it be done," a pro-Laetrile physician told a Senate subcommittee chaired by Edward Kennedy in 1977, "it will be an absolute sham." "You do not and cannot expect to get results from Laetrile treatment," Robert Bradford said at the FDA hearing, "unless you are a trained metabolic physician."

This quotation points to the latest change in Laetrile's status, its envelopment in the broader cloak of metabolic and holistic medicine. In a recent book, *Now That You Have Cancer,* Bradford has likened the metabolic program to a crown containing nine jewels, with Laetrile "the crown jewel within the diadem," the others, including diet, detoxification, minerals, enzymes, and vitamins, equally necessary for the control of cancer. In view of this complexity, whatever a National Cancer Institute trial may reveal, disputes between advocates of orthodoxy and champions of unorthodoxy seem certain to continue. Each system dwells, as Ernst Krebs, Jr., has put it, "in a different universe."

In the longer version of this paper, I have sketched a ten-point profile of health quackery, based on a study of its history, with particular attention to the three major cancer unorthodoxies of the last half century, Dr. William Koch's Glyoxilide, Harry Hoxsey's mainly botanical dosages, and Krebiozen, imported from Argentina by the Durovic brothers and brought to prominence by the espousal of Dr. Andrew Ivy. The points of this profile are: (a) the exploitation of fear; (b) the promise of painless treatment and good results; (c) claims of a miraculous scientific breakthrough; (d) the tendency to rely on a unitary explanation for disease and a single entity or system for combating it; (e) frequent resort to the Galileo ploy—the assertion that, while the community of scientists may criticize me now, future generations will do me honor; (f) the conspiracy theory—the charge that establishment scientists conspire to suppress hopeful innovations because such developments threaten to undermine power, prestige, and positions; (g) a great agility at adjusting theory and tactics to meet changing circumstances; (h) a reliance on testimonials in seeking to make a case for therapeutic success; (i) the distortion of the idea of "freedom"; and (j) the involvement of great sums of money. The Laetrile movement, it seems to this historian, conforms to such a profile.

Fear of cancer, suspicion of government, a primitivistic retreat from complex civilization to so-called "natural" ways, skillful organization, adept lobbying, and a shrewdness at borrowing time-tested techniques from unorthodoxy's well-stocked past, such factors have undergirded Laetrile's astounding impact upon our times.

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This paper is based in part on Food and Drug Administration records concerning Laetrile, including the FDA Administrative Record, Docket No. 77N-0048, called for by the Court of Appeals for the Tenth Circuit, and the resulting Commissioner's Decision on Status, *Federal Register,* 42, 39773 (1977). Important information appears in *Banning the Drug Laetrile from Interstate Commerce by FDA* (95th Congress, 1st session, Hearing before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, U.S. Senate, July 12, 1977). Articles on Laetrile are numerous; important recent articles include: Anon., *Consumer Reports* 42, 444 (1977); A.A. Checchi, *Assoc. Food & Drug Officials Q. Bull.* 42, 91 (1978); R.T. Dorr and J. Paxinos, *Ann. Internal Med.* 89, 389 (1978); N.M. Ellison et al., *N. Engl. J. Med.* 299, 549 (1978); D.M. Greenberg, *West. J. Med.* 122, 345 (1975); C. Holden, *Science* 193, 982 (1976); F.J. Ingelfinger, *N. Engl. J. Med.* 296, 1167 (1977); W.J. Janssen, *Analytical Chem.* 50, 197A (1978); T.H. Jukes, *Nutrition Today* 12, 12 (Sept.-Oct. 1977); J.P. Lewis, *West. J. Med.* 127, 55 (1977); M.P. Lipset and J.C. Fletcher, *New Engl. J. Med.* 297, 1183 (1977); G.E. Markle, J.C. Petersen, and M.O. Wagenfeld, *Soc. Sci. & Med.* 12, 31 (1978); C.G. Moertel, *N. Engl. J. Med.* 298, 218 (1978); S.L. Nightingale and F.D. Arnold, *Legal Aspects of Med.* 6, 31 (1978); F.P. Smith et al., *JAMA* 238, 1361 (1977). Among works consulted written by Laetrile proponents are G.D. Kittler, *Control for Cancer* (Paperback Library, New York, 1963); R.W. Bradford, *Now That You Have Cancer* (Choice Publications, Los Altos, CA, 1977); and J.A. Richardson and P. Griffin, *Laetrile Case Histories* (Bantam Books, New York, 1977).

# A Regional Model for a Hospital-Based Clinical Engineering Internship Program

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**ABSTRACT—In this article the operation and experiences obtained during the evolution of a "regional-based, hospital-orientated clinical engineering internship program" are presented. This type of educational program has involved major medical institutions in the education of clinical engineers. It has been designed to provide graduate engineering students an opportunity to pursue their graduate studies while totally immersed in the clinical environment. This approach to the education of clinical engineers offers an indepth and rigorous clinical experience to match the engineering expertise gained in the classroom. The development of such inter-institutional and interdisciplinary programs are considered necessary to insure the growth and vigor of this new enterprise—clinical engineering.**

## Introduction

In recent years, the impact of technology upon the delivery of health care has been profound.[1] In an effort to assist the health professional effectively utilize this "continually changing technology" as they treat patients in their care, an increasing number of engineers have been employed in clinics and hospitals.[2] These so-called "clinical engineers" have been called upon to perform a variety of tasks ranging from the development and procurement of equipment to the education and training of hospital personnel in the safe utilization of modern medical systems. In a few institutions, properly managed groups of engineering professionals have succeeded in enabling the hospital to cope with their vast arsenal of medical devices; and, at the same time, reduce the cost of purchasing, maintaining and effectively utilizing the modern medical marvels (such as, echocardiography, computerized tomography, etc.) technology has provided.[3-6]

In order to properly prepare engineering professionals for increasing roles in the delivery of health care, a unique program—"*A Clinical Engineering Internship Program"* was established in the region of greater Hartford, Connecticut in September 1974.[7] Initiated by the cooperative efforts of Trinity College, the Hartford Graduate Center, and Hartford Hospital, *this hospital-based, two-year internship program* has evolved to include the St. Francis Hospital and Medical Center, and the University of Connecticut Medical Center Dempsey Hospital. This inter-institutional program offers a regional approach to provide an indepth and rigorous clinical experience to match the engineering expertise gained in the classroom. This article outlines the operation and experiences obtained in developing a regionally based, hospital-oriented clinical engineering internship program and may be of particular interest to both academic and medical institutions involved in the education of clinical engineers.

## Operation of Hospital-Oriented Clinical Engineering Internship Program

Traditionally, training in health care has included in-house training. Physicians, nurses, medical technologists, etc., have all utilized practical experience to

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help develop their professional skills. If one viewed the hospital as a major employer of "clinical engineers," then, it may be reasonable for these prospective employers to expect that these new professionals also have such an experience. During the past five years, it has become quite apparent that not only would hospitals desire their new employees to have this experience, they would also like to have a role in providing it. Thus, apart from the academic requirements designed to provide graduate level competence in a specific engineering field (such as electrical engineering, mechanical engineering, computer science, etc.), the primary objectives of this program may be enumerated as follows:

1) Provide an exposure to hospital organization and administrative functions.
2) Permit hospital experience in clinical engineering; that is, provide an opportunity to apply engineering techniques to patient care and hospital based research.
3) Provide substantial experience working with hospital personnel including administrators, nurses, technicians and medical staff.

These objectives are not traditional classroom experience, but rather emphasize the practical side of health care technology. All of these experiences are obtained during the "internship" which consists of two phases: a) a rotation through a majority of the departments within the hospital during the first year of the internship, and b) an indepth involvement with a clinically oriented research project during the second year of the program. Since the program requires that the entire two academic years be spent working 20-25 hours per week at the hospital with the remaining time concentrated in classroom activities, there is ample time for the student to be engaged in a thorough indoctrination of hospital operation and procedures. While being immersed in the clinical environment the student usually takes two graduate courses each semester for four semesters (i.e., a total of eight graduate academic courses). In addition, two course credits are given for the student's research activity which is accomplished during the second year of the program and constitutes a thesis project. Therefore, the entire graduate program consists of ten courses (each three credits) or, a total of 30 credit hours. Since these courses are provided during his stay in the hospital, the student can select those courses which may be most helpful to him as he profits from his experience in the clinical environment.

## Two Phases of the Internship Program

During the first year the student works in the hospital by rotating through various departments (such as plant engineering, emergency room, operating room, cardiac and pulmonary laboratories, etc.). As a result, the student is essentially considered part of the staff of that department during his stay; and although his primary experience is one of exposure to the operation and functioning of the personnel and equipment within that department, he is expected to perform assigned tasks that would also be of service to that department. (See Figure 1.) For example, while in physical medicine, one intern developed a biofeedback device which was linked to a radio to allow a patient to know if he was working his muscles hard enough, the louder the radio, the harder he was working. In another instance, during a rotation in the emergency room, another intern was given the task of assisting in the design of new out-patient facilities being constructed, and report a summary of the conclusions reached to the house-staff. These experiences have demonstrated to us that the intern can absorb the daily routine procedures within the departments quite rapidly and in the process his exposure to patients, nurses and hospital staff permits all parties to become familiar with the roles each can play as a member of the health care team.

Figure 1
Equipment repair and calibration is a routine activity. Within the clinical engineering department of the hospital, the operation and maintenance of a large variety of medical devices are demonstrated to the intern during his first year of rotation. This educational process is greatly enhanced by the presence of the second-year intern.

During the second year, the student intern undertakes a hospital oriented research project in the area of his particular interest. This thesis activity has a two-fold purpose: (1) to enable the student to participate in an activity that will be of value to the hospital, and (2) to satisfy the requirements for a Master of Science degree. This activity has provided an excellent opportunity for department managers to investigate problems otherwise impossible. In addition, it has encouraged the staff of these clinical departments to interact with engineering faculty, thereby facilitating discussions pertaining to operation and future equipment purchased by the hospital

Figure 2
In the pulmonary laboratory, the intern is instructed to conduct exercise or "stress" tests to determine the overall cardio-pulmonary capacity of patients. This test is presently being viewed as a screening procedure to detect oxygen consumption, pulmonary blood flow and cardiac output.

(see Figure 2). For example, in one case, the thesis activity involved adapting the rebreathing techniques presently being utilized on adults in the pulmonary laboratory of Hartford Hospital to young children (neonates).[8] This project actively involved members of the medical staff, engineering faculty as well as our students, and led to the development of a valvular system to accomplish the desired objective and became the pilot data for a successful grant proposal. Although it is not expected that all master's thesis activity will be this successful, it does illustrate the potential for the involvement of our graduate students in worthwhile clinical research projects.

### Important Aspects of the Program

This program is tuned to the needs of the individual intern and, consequently, constitutes an *apprentice type training experience*. However, for this to occur, a high degree of interinstitutional cooperation between the academic and medical components of the program has been required and achieved on a regional level. Several interesting aspects of this arrangement should be noted. For this type of program to be effective, it must be mutually beneficial to all concerned—the student, the university and the hospital. First, the students obtain an excellent education. They tend to be highly motivated, enjoy the clinical exposure and readily work overtime to gain additional experience. Second, the academic institutions are able to provide health care oriented projects for students within the health care system. The hospital, in return, has begun to feel the impact of an expanded biomedical engineering program without being committed to additional permanent positions or having to make major equipment purchases. The regional nature of this program has the additional advantage of facilitating cooperation among the medical institutions (see Figure 3).

It has been our goal to provide a high quality educational program for a small number of students. The "internship" approach is not appropriate for large numbers of students. Nor is it desirable for large numbers of "clinical engineers" to be trained when the market for significant numbers of this type of professional is still not clear. It is our feeling, however, that this market will continue to increase as these professionals are encouraged to enter the medical instrumentation component of the industrial community, the various federal agencies responsible for medical device regulation, or engineering arm of the various insurance companies underwriting hospital and malpractice insurance policies.

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Figure 3
Interns from the hospitals involved in this regional program have also engaged in exchange visits to experience the activities and attitudes in the nearby medical institutions. As illustrated above, Ellen Fletcher, first-year intern at Hartford Hospital, is being given a demonstration of equipment at St. Francis Hospital and Medical Center by the second-year intern there, Sheldon Geldon. Such an exchange greatly expands the educational horizons of the student and encourages cooperation and communication between the medical facilities involved.

Our graduates have been quite successful in gaining employment upon completion of our program and have entered both the industrial and medical sector of our society. Two of our interns have decided to enter industry, one in a company engaged in the development of prosthetic devices and the other in electronic medical instrumentation. Another was asked upon graduation to take over as the director of the pulmonary laboratory at Hartford Hospital—evidence that the hospital participating in this program could utilize the talents of the individuals it was training. Two other individuals were accepted into medical school during their first year of rotation. It is our strong feeling that in all of these cases it shows that such an educational investment in these individuals as well as those presently engaged as interns (n=5) will in the long run be quite beneficial to individuals themselves, the engineering profession, and the acceptance of technology in the medical arena.

### Conclusions

Just as the hospital internship benefits the hospital, the academic institutions and the students on a short term basis, long range benefits of such programs are also becoming apparent. The clinical engineer has been described as an engineer who is able to solve difficulties involving patient care equipment in a health care facility and who has the knowledge and experience to work as a partner with health professionals to plan and implement appropriate programs for improving health care delivery. However, the extent to which they are accepted and sought after depends upon several key factors: the quality of the students, the quality of their training and the quality of their performances. All of the courses are related. Students graduating from "clinical engineering" programs must be as competent as their contemporaries trained in traditional engineering fields. The depth and rigor of this engineering education must, however, be complemented by practical clinical experience. The "internship approach" can provide this experience and in particular the type of hospital based internship program described here offers an indepth and rigorous clinical experience to match their engineering expertise. Such programs are necessary to insure the growth and vigor of this new profession that links medicine and engineering.

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## Conflict of Interests—or Is There?

Just as the object of a trade union under existing conditions must finally be, not to improve the technical quality of the work done by its members, but to secure a living wage for them, so the object of the medical profession today [1906] is to secure an income for the private doctor; and to this consideration all concern for science and public health must give way when the two come into conflict. Fortunately they are not always in conflict. Up to a certain point doctors, like carpenters and masons, must earn their living by doing the work that the public wants from them.

—George Bernard Shaw, *The Doctor's Dilemma*, Preface.

# The Hospital Component of the Consumer Price Index: How Good Is It?

P. JOSEPH PHILLIP, Ph.D.

The Carter Administration's sustained efforts to have a mandatory hospital cost control legislation enacted, and the recent white paper on the President's anti-inflation program which stipulates that the appropriate components of the government's price index will be used to monitor the performance of industries raise the question: What is the connection between the movement of the Hospital Component of the CPI—the government's version of inflation in the hospital sector—and real inflation in the hospital sector? As we shall see presently, the connection is far more tenuous than is commonly believed.

In 1972, the Bureau of Labor Statistics (BLS) introduced the Hospital Service Charge (HSC) as a component of the CPI. This component is based on the prices charged from direct-pay consumers for Semi-Private Room, Operating Room and 8 ancillaries. There are two reasons why the HSC grossly exaggerates inflation rate in the hospital sector. First, people do not buy hospital care the same way they purchase groceries from the supermarket. Over 80 percent of hospital services are paid for by intermediaries such as Blue Cross and by government under social programs such as Medicare and Medicaid. There is no direct relationship between the amount reimbursed by intermediaries and the prices charged from direct-pay consumers. Indeed, the relationship is an inverse one. When the intermediaries limit or disallow charges, hospitals are apt to hike charges made on direct-pay customers to recover part of the lost revenue. Thus, the charge-based HSC has a strong upward bias. Second, the HSCI has methodological flaws. In order to measure pure price changes, it is imperative that we hold constant the quantity of whatever we are pricing. We cannot, for example, measure price changes of milk unless we specify a certain fixed quantity such as "one gallon." Now, the major components of HSCI, namely, Semi-Private Room and Operating Room are not defined in terms of a fixed quantity. Take, for example, Semi-Private Room where charges are measured in units of time—a day. As we know only too well, a great deal or very little can happen during a 24-hour time-span. Thus, time is no satisfactory unit of quantity. In the hospital setting, "service intensity," i.e., the quantities of various services provided per typical patient day have been constantly rising. The following table which shows the rates of increase in the quantities of selected services provided per typical patient day speaks for itself.

| *Service* | *1969 Qty* | *1976 Qty* | *Percent Qty* |
|---|---|---|---|
| Nuclear Medicine Procedures | 0.007 | 0.035 | 400% |
| Occupational & Recreational Therapy Manhours | 0.011 | 0.030 | 173% |
| Pharmacy Line Items | 0.962 | 2.393 | 149% |
| Intravenous Therapy Manhours | 0.012 | 0.028 | 133% |
| Inhalation Therapy Manhours | 0.131 | 0.295 | 125% |
| Clinical Lab Tests | 2.343 | 4.998 | 113% |
| Therap. Radiol. Procedures | 0.014 | 0.023 | 64% |
| Diag. Rad. Procedures | 0.304 | 0.468 | 54% |

Since service intensity has been rising, the price data obtained by the BLS for Semi-Private Room and Operating Room reflect, in reality, the combined effects of inflation and quantity increases. One can easily verify this by comparing the historical price increases of these components with those of ancillaries which are defined with greater specificity and are, therefore, more indicative of true inflation. For example, during 1972-77 when Semi-Private Room and Operating Room prices were registering annual increases of 14.5% and 16.9% respectively, the prices of Antibiotics, Oxygen and Tranquilizers were increasing only at 6.5%, 7.8% and 8.1% respectively.

Beginning with January 1978, the BLS discontin-

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ued the Hospital Service Charge Index. Semi-Private Room is redefined as "Hospital Room" (all types of accommodations), and a new index, "Other Hospital and Medical Care Services" was introduced. The latter is based on three components: (1) Hospital Ancillary Services, (2) Emergency Room Services and (3) Nursing and Convalescent Home Care Services. The inclusion of the last-named, rendered the new index clearly unsuitable to measure price changes in short-term, general hospitals. One is therefore forced to focus on the price movement of "Hospital Room" which had been, as we have seen earlier, one of the least satisfactory components of the defunct HSC.

The bottom line is that the BLS indexes continue to present an exaggerated picture of price increases in the hospital sector. It is due to this reason that the American Hospital Association developed its own indexes, the Hospital Cost Index (HCI) and the Hospital Intensity Index (HII), and have already begun publishing these indexes in its journal *Hospitals* (see, for example, the November 1 issue). Unlike the BLS indexes, the HCI is based on incurred cost, and thus it steers clear of the bias due to the discrepancy between charges and reimbursements. Again, unlike the BLS indexes, HCI is constructed from some 46 components whose quantities are held constant. It is the position of the American Hospital Association that the HCI, which has been rising all along at a much slower pace than the Hospital Service Charge Index of the BLS, provides a more accurate measure of inflation in the hospital sector.

A question that needs to be answered at this point is: Why do hospital expenditures rise so fast if inflation in the hospital sector is not all that excessive? The answer is simple, so simple in fact that one wonders why it has been overlooked all these years. Our total expenditure is a function of price and the quantity consumed. For example, we will have a big gasoline bill if we purchase larger quantitities of gasoline even if the price per gallon remains unchanged or has risen only in line with general inflation. It is precisely this situation that prevails in the hospital sector. For a variety of reasons into which we cannot go, Americans are consuming increasing quantities of health care. The Association's Hospital Intensity Index (HII) shows that the quantities of services provided per typical patient day is rising at an annual rate of 4-5 percent. It is the increased consumption of hospital care occurring on top of prevailing price increases that causes hospital expenditures to escalate so rapidly. Washington policy makers have either not grasped the full import of this situation or they have chosen to ignore it because it is politically more expedient to blame things on "excessive inflation" in the hospital sector than to face candidly the broader and sensitive issue of burgeoning consumption of hospital care.

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EDITOR'S ADDENDUM:

MAY, 1979, WAS THE FOURTH STRAIGHT MONTH in which inflation in the general economy was greater than the rate of increase in health care costs. The all-items component of the Consumer Price Index rose 1.2%, compared to 0.5% for the medical care component. Physicians' services increased 0.7% during the month, and hospital room charges rose 0.4%.

During the past 12 months the all-items index has risen 10.8% and the medical care component has gone up 8.9%. Physicians' services have risen 9.1% and hospital room charges 11.3% during the period.

—*AMA Newsletter,* July 9, 1979

# Chronology: Antitrust Actions in Health

## Introduction

A. This chronology seeks to portray antitrust activities of the Federal Trade Commission, the Antitrust Division, Department of Justice, and Congress from mid-1975 through mid-1978. Virtually all antitrust activity in the health field has occurred during this period. Although every effort has been made to produce a complete chronology, the complexity of the field, bureaucratic differences, and the secrecy which surrounds this area make it difficult to assure the reader that every item has been successfully identified. Almost all items refer to FTC actions. In some instances legislative oversight and other related activities have also been included to give the reader a broad picture of activity in this field. Some events not directly involving law enforcement are also included.

B. Almost all actions taken by the FTC in health related fields have occurred since mid-1975. Prior to that period investigations concentrated on alleged anti-competitive business practices in the pharmaceutical industry. This chronology provides an indication of the scope and pace of FTC initiatives. It concentrates on publicly announced actions, but includes some nonpublic actions as well. The list is not exhaustive because the FTC is conducting nonpublic reviews and investigations for which we have no information, some of which will be settled and made public in the coming months. Several items listed refer to the same investigation.

C. Bear in mind the following when reviewing this chronology:

(a) The existence of an investigation does not imply guilt of any party.

(b) All investigations are secret, although public comments are requested when a public announcement of an investigation is made.

(c) Consent agreements are for settlement purposes and do not constitute a legal admission of guilt. They carry the force of law with respect to future actions and civil penalties can be imposed if they are violated.

D. Items appearing under 1975 and 1976 appeared in a previous *Note.* They have been revised and updated. Some additional items have been added for these two years.

## 1975

*June 1975: Advertising prescription drug prices.* FTC proposes a rule allowing pharmacies to advertise retail prices for prescription drugs.

*July 1975: Cephalosporin marketing (nonpublic).* A preliminary investigation to determine whether FTC and Clayton Act violations occurred in development and marketing of a widely used antibiotic. Involves Eli Lilly and Company. FTC still collecting information after initial court challenges.

*September 1975: Antitrust suit against anesthesiologists.* Department of Justice files antitrust suit against the American Society of Anesthesiologists, Inc. alleging that the Society restricted fee competition.

*October 1975: Advertising prescription drug prices.* FTC announces public hearings in three cities on a proposed trade regulation rule on disclosure regulations concerning prices for prescription drugs.

*November 1975: Advertising for OTC drugs.* FTC proposes a trade regulation rule for over-the-counter (OTC) drugs prohibiting the making of any product claims in advertising which the FDA prohibited in labeling under its over-the-counter drug review program. The Commission believes that the advertising of a drug that the FDA has determined unsafe is a deceptive and unfair practice. (See below).

*November 1975: Antitrust suit against pharmaceutical associations.* Department of Justice files antitrust suit against American Pharmaceutical Association and Michigan State Pharmaceutical Association alleging that they conspired to prohibit advertising of retail prices by members of their respective associations.

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*December 1975: AMA complaint.* FTC issues formal complaint that the AMA has illegally restrained competition among medical doctors by preventing physicians from advertising and engaging in price competition. (See below).

*December 1975: Advertising eyeglasses.* A trade regulation rule to permit advertisements dealing with the price and availability of prescription eyeglasses was proposed. The rule is intended to allow sellers and providers of ophthalmic goods and services to disseminate accurate information regarding the price and availability of prescription eye wear. (See below).

*No date: Health maintenance organizations (nonpublic).* A continuing economic investigation to determine if there are existing professional or other practices which impede the development of HMO's as an alternative form of service delivery. The Blue Shield consent order in Spokane, Wash., noted below, results from this investigation.

**1976**

*January 1976: Competition in eye services.* FTC authorizes investigation into providers and sellers of ophthalmic goods and services to determine whether there is a violation of FTC Act. Concerned with certain alleged practices in prescription eyeglass industry which may restrain trade, e.g. limitations on the number of branch offices an industry member may own or operate; prohibitions on the employment of optometrists or opticians by retailers; etc.

*January 1976: Advertising eyeglasses.* Releases staff report on alleged restrictive practices regarding eyeglass advertising, especially restrictive state laws and prohibitions by private professional associations on eyeglass prices. Proposes trade regulation rule that would permit advertising by sellers and providers of ophthalmic goods and services.

*February 1976: AMA complaint.* A prehearing conference was held on the findings of the FTC that certain practices of the AMA, especially regarding the alleged restrictive effects of professional codes of ethics, were in violation of the FTC Act by limiting competition. Trial set.

*February 1976: Physician fee setting—Blue Shield.* FTC announces investigation into individual plans and National Association of Blue Shield Plans to determine whether Blue Shield-physician relationship has an unfair effect on competition, e.g. establishment of fee levels. Possible results could include dropping inquiry because there is no "reason to believe" a violation of FTC statutes exists: issuance of a proposed trade rule; staff report; report to Congress; or litigation.

*March 1976: FTC oversight hearing.* House Subcommittee on Oversight and Investigations holds hearing on FTC activity. Notes health activities as one example of increased activity. Criticizes delay in other industry wide investigations.

*April 1976: Advertising eye services.* Public hearing announced for summer in five cities on proposed trade regulation rule concerned with ophthalmic goods and services. (See below).

*April 1976: AMA manpower investigation.* FTC announces investigation to determine whether AMA has illegally restrained supply of physicians and health care services through activities related to accreditation of medical schools and graduate programs; definitions of fields of practice for physicians and allied health care personnel; limitations on forms of delivery inconsistent with fee-for-service mode.

*May 1976: Drug firm merger.* Rules that the acquisition by Warner-Lambert of Parke, Davis Co., two large pharmaceutical manufacturers, substantially lessened competition in several specific drug markets and was in violation of the Clayton Act.

*July 1976: Relative value scales.* Accepted a consent order agreement, now final, from two specialty societies which agree to stop using relative value scales as guides for pricing professional services. The societies were the American Academy of Orthopaedic Surgeons and the American College of Obstetricians and Gynecologists (ACOG). These are the first corrective steps taken by the FTC in its current health care program, and the first actions taken by the agency against relative value scales. The agreements resulted from a staff complaint that the societies had prepared, published and circulated scales that had the effect of establishing, maintaining or otherwise influencing fees charged by their members.

*July 1976: JCAH and psychologists (nonpublic).* In response to a written complaint from the Association for the Advancement of Psychology, the lobbying arm of the profession, a preliminary investigation is started. The private complaint alleges that the Joint Commission on Accreditation of Hospitals and its constituent groups engage in unfair competitive practices in violation of Section 5 of the FTC Act by denying accreditation to hospitals which allow psychologists to have staff privileges. FTC suspends action pending possible actions in hospital privileges area.

*July 1976: Dental labs (nonpublic).* The San Francisco regional office initiates an investigation of state laws or regulations which prevent dental labs from selling dentures directly to the public. The intention is to determine whether these rules, which require sales to be made only through licensed dentists, unfairly impede competition.

*July 1976: Egg advertising.* A cease and desist order is issued against the National Committee on Egg Nutrition, an egg producers' association, to stop deceptive advertising that "there is no evidence that eating eggs, even in quantity, increases the risk of heart attack."

*August 1976: Multiple source drugs.* FTC authorizes investigation into prescription drug practices to determine whether consumers are subject to unfair or deceptive acts where prescription drugs can be filled from several sources, but are not so filled because of existing state law or private action. FTC argues that about 40% of all prescriptions, or $3 billion worth, are for drugs manufactured by more than one company. Its inquiry concentrates on whether pharmacists should be free, if the physician does not object, to select the least expensive drug prescribed for a patient; whether and to what extent consumers would save if doctors delegated more authority to pharmacists to select drug sources; whether price competition is unfairly impeded in this area because of state law or private action.

*September 1976: Nursing homes.* FTC authorizes investigation of proprietary nursing home industry to ascertain if there have been violations of the FTC Act.

*September 1976: Advertising eye services.* Additional hearings in Washington announced for two special witnesses to present studies. Hearing record now closed and under review.

*September 1976: HMO-physician group consent order.* A consent order is accepted wherein a Blue Shield organization in Spokane, Wash., and its participating physician group agree to stop alleged boycotting of HMO physicians and patients. The order prohibits exclusion of any lawfully practicing physician from being a participating physician in the Blue Shield Plan, discrimination against physicians because they participate in an HMO or practice on anything other than a fee-for-service basis.

*September 1976: Hearing aid competition.* An administrative law judge ruled in an initial decision that one of the nation's leading hearing aid manufacturers, Beltone Electronics Corp., was restraining competition in the distribution of its product. The initial order would prohibit the alleged acts. (See below).

*October 1976: Drug merger.* FTC issues final orders requiring partial divestiture of Warner-Lambert and Parke, Davis Co. assets because of anticompetitive merger. Several alleged violations not proved.

*October 1976: Advertising OTC drugs.* FTC announced a public hearing for January, 1977, on a proposed trade regulation rule concerning advertising of over-the-counter drugs.

*November 1976: Accreditation protest.* As result of AMA manpower investigation (above), FTC Bureau of Competition files letter with U.S. Office of Education stating that the Liaison Committee on Medical Education "should be denied" recognition as the voluntary agency to accredit medical schools because of an alleged conflict of interest established by the relationship between the Committee and the AMA. (See below).

*November 1976: Relative value scales.* The FTC announced acceptance of a consent order prohibiting the American College of Radiology from using relative value scales. The order remains open for public comment till January 17, 1977. The order was based on a staff report and complaint which alleged that ACR scales set forth comparative values for surgical and medical procedures and services on non-monetary units, but were convertible to a monetary fee by application of a dollar conversion factor. The staff report published by the FTC as the basis of the order claimed that the use of scales froze the relationship of different fees for different procedures even where individual professionals applied their own dollar factors to each relative scale.

### 1977

*January 1977: FTC and medical appliances industry: oversight.* FTC and Department of Justice asked by Representative Claude Pepper, Chairman of the Select Committee on Aging Health Subcommittee, to investigate medical applicances industry's alleged exploitation of the elderly and report back to the subcommittee in 60 days. Request made following Health and Long-Term Care Subcommittee report on "Medical Appliances and the Elderly: Unmet Needs and Excessive Costs." (FTC responded by outlining what investigations it already had underway, but did not submit specific report requested.)

*January 1977: Advertising eyeglasses: oversight.* Bureau of Consumer Protection testifies before the Monopoly Subcommittee of the Senate Small Business Committee on state restrictions against advertising eyeglass prices.

*January 1977: Physician manpower investigation.* FTC serves subpoenas on 30 medical societies seeking information on the supply of physicians and allocation of specialties and allied medical fields. Subpoenas seek information on whether there has been collusion affecting the supply of medical specialists.

*January 1977: ADA complaint.* FTC votes to issue complaint alleging that American Dental Association has illegally restrained competition in violation of the FTC Act by preventing advertising and price competition among dentists.

*February 1977: Antitrust suit against podiatrists.* Justice Department files antitrust suit against Illinois Podiatry Society, Inc. charging that Society restricted fee competition.

*February 1977: Advertising of OTC drugs.* Hearing open on proposed FTC rule to limit the type of claims made for over-the-counter drugs and the language used in advertisements for them. Rule would allow claims to be made in advertising only if found allowable in labeling by the Food and Drug Administration.

*April 1977: Drug marketing report.* FTC issues staff report entitled "Sales, Promotion, and Product

Differentiation in Two Prescription Drug Markets." The report studies two markets and concludes that "the first firm to offer and promote a new type of product received a substantial and enduring sales advantage." The researchers also conclude that the physician preference for prescribing a relatively small number of brandname drug products was "probably a rational response" to the proliferation of products available from the drug industry. Study suggests that consideration be given to repealing state antisubstitution laws, and limiting brand-name trademark protection for prescription drugs.

*April 1977: Health Maintenance Organizations.* FTC announces that Bureau of Competition will send letter of inquiry to approximately 200 Health Maintenance Organizations asking for information on anti-competitive restraints against them which may have hindered their development.

*April 1977: Relative value scales.* FTC obtains consent settlements in which relative value scales are no longer to be used by the Minnesota State Medical Association and its 34 affiliated county societies. (Similar consent agreements issued with the American College of Obstetricians and Gynecologists, American Academy of Orthopaedic Surgeons, American College of Radiology.)

*May 1977: FTC legislative authority over nonprofits.* Committee on Interstate and Foreign Commerce votes to delete provision in FTC amendment (HR 3816) which would grant commission authority over non-profit organizations.

*May 1977: Accreditation protest.* FTC Bureau of Competition writes Commissioner of Education, Office of Education, recommending that it reconsider past practice of granting sole medical school accreditation authority to the Liaison Committee on Medical Education (LCME) based on FTC's concern about conflict of interest inherent in AMA's domination of the LCME, "whose decisions govern entry into the profession . . . ," and FTC's opinion that the LCME did not comply with the Office of Education's criteria for recognition. FTC recommended that accrediting power be vested in autonomous groups with broad-based representation. (O.E. subsequently extends LCME's authority for two, rather than four, years.)

*May 1977: Advertising eyeglasses.* FTC receives staff report recommending a rule to promote advertising of prescription eyeglasses, and provide for the unconditional release of eyeglass prescriptions to patients without assessment of additional charges or fees.

*June 1977: Conference on competition in health care sector.* FTC Bureau of Economics sponsors conference on "Competition in the Health Care Sector: Past, Present, and Future." The two-day conference discusses various elements of competition among physicians, hospitals, health insurers, as well as competition from alternative delivery systems. Concluding discussions were devoted to competition, regulation, and their respective roles in cost containment.

*June 1977: FTC rulemaking procedures.* FTC issues guidelines for public participation in rulemaking. Procedures are established for the direct presentation of views to the Commissioner in rulemaking proceedings, following which persons interested in the Ophthalmic Goods Trade Regulation Rule pressed their viewpoints personally before the full Commission.

*June 1977: Advertising eyeglasses.* FTC releases staff report on proposed Trade Regulation Rule regarding ophthalmic goods and services.

*July 1977: Nursing homes.* FTC sets up task force to examine possible infringement of basic consumer rights by nursing home operators.

*July 1977: Antitrust oversight.* Senator Edward Kennedy holds first joint hearings of Subcommittees on Antitrust, and Health and Scientific Research. Subject: prescription drug prices.

*July 1977: Medical laboratories.* FTC accepts agreement containing a consent order prohibiting Damon Corporation of Needham, Mass., for a 10-year period from acquiring without FTC consent independent medical laboratories in 12 geographic areas where Damon currently has substantial operations, and from obtaining laboratory testing business through rebates to physicians.

*July 1977: Health Maintenance Organizations.* FTC issues staff report entitled "The Health Maintenance Organization and Its Effects on Competition," which concludes that HMO's have had a competitive impact on the customary fee-for-service medical system.

*September 1977: AMA complaint.* FTC opens administrative hearings on its complaint against the AMA and two Connecticut medical societies that free competition is restrained by the AMA code of ethics which places restriction on advertising and on the entry of new physicians into practice.

*December 1977: Advertising eye services.* FTC tentatively adopts rule eliminating advertising restraints by optometrists and ophthalmologists.

*December 1977: Competition among health insurers.* FTC Bureau of Economics initiates study of competition among health care insurers to identify factors that contribute to the inability of private insurers to implement effective cost-control measures.

*December 1977: Pertschuk-Califano meeting.* First meeting between FTC Chairman Pertschuk and HEW Secretary Califano, following which staffs of both agencies begin cooperating to avoid duplication and conflicts.

*December 1977: Antitrust suit against podiatrists.*

February 1977 Department of Justice complaint settled against Illinois Podiatry Society. Prohibits use of RVS.

### 1978

*January 1978: ADA complaint.* FTC sets trial date in September 1978 in its restraint-of-competition case against the American Dental Association.

*January 1978: Bureau of Consumer Protection reorganization.* FTC's Bureau of Consumer Protection is reorganized to create eight divisions, among them the Division of Food and Drug Advertising and the Division of Professional Services, which will have the power to investigate the prescription drug industry.

*February 1978: Children's advertising.* FTC Bureau of Consumer Protection staff recommends that the Commission ban television advertising on programs in which the audience is comprised substantially of children six years old and younger. Staff recommendation also calls for ban on television advertising of heavily sugared foods directed toward children ages 7 through 12 suggesting that those commercials be scheduled only after 9:00 p.m. Staff report also calls for corrective advertising to present health, safety or nutritional information about other products advertised to the 7-12 group.

*March 1978: Oversight hearing—Blue Shield.* Congressman John Moss, Chairman of House Subcommittee on Oversight and Investigations, calls hearing "to examine the composition of Blue Shield boards, including the extent of doctor domination . . . " FTC Chairman Pertschuk and Blue Cross-Blue Shield president McNerney testify.

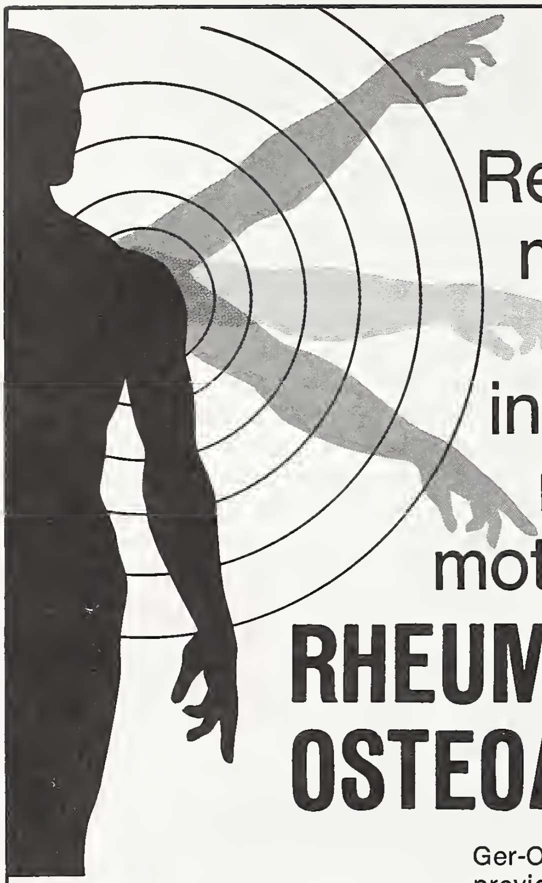
*March 1978: Relative value scales.* FTC accepts consent order requiring California Medical Association to stop publishing or participating in development of relative value studies and withdraw those already published.

*May 1978: AMA complaint.* Oral arguments in trial before administrative law judge end. Briefs due July 1978. Initial decision due fall 1978. Decision may be appealed within FTC and judicially.

*May 1978: Revision of food and drug laws.* FTC Chairman Pertschuk writes to OMB to criticize the provisions in HEW's proposed revision of the food and drug laws which would eliminate strict criminal liability of executives of companies found to have sold faulty drugs.

*May 1978: Eyeglass advertising rule.* FTC decides unanimously to order that restrictions on the advertising of the prices of eyeglasses be removed. Order also requires that prescriptions be given to consumers following eye examinations to make comparison shopping easier. American Optometric Association will challenge the decision in court on the grounds that FTC has overstepped its regulatory authority. American Optometric Association announces intention to seek judicial stay.

*May 1978: National Health Insurance comments.* FTC Chairman Pertschuk writes to White House commenting on alternative NHI plans and expressing position that careful consideration be given to "Consumer Choice Health Plan," option most closely associated with operation of the free market mechanism.



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**1. Gordon, E. E. and Haas, A., Indust. Med. & Surg. 28:217, May, 1959.**

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# Genetic Counseling

### Physicians May Be Held Liable In Abnormal Births

In two companion cases, **Becker v. Schwartz** and **Park v. Chessin** (Dec. 1978), the New York State Court of Appeals has ruled that a physician may be held liable for the monetary loss sustained by the parents if the physician negligently fails to inform a couple of the risks they face of bearing an abnormal child. Should the patient then give birth to an abnormal child, the doctor may be required to pay the lifelong special costs for caring for it.

### The Implications

The court's ruling in New York implies that a physician should not act as an implacable judge of the best course of action in pregnancies where risk of abnormal birth is a factor. Ultimately, the patient has the right of final decision. It thus becomes a doctor's duty to inform and advise: in short, **counsel** the patient so that she can make an intelligent decision after consideration of the available options. (While this ruling has the force of law only in New York State at present, other states may look to this case as a precedent.)

### The Function of Genetic Counseling

Genetic counseling aids in determining the mathematical odds of producing a child without genetic defects. 85% of congenital disorders are not subject to prenatal diagnosis, and risks must be inferred from circumstances and medical history. Detection of the remaining disorders is possible through various tests, including Amniography, Ultrasound, Amnioscopy, Placental Aspiration, Maternal Blood Screening, and Amniocentesis.

Patients general considered to be at risk, and for whom genetic counseling is recommended by the American College of Obstetricians and Gynecologists are:

—Women over age 35.
—Couples who have already given birth to a child with genetic disease.
—Couples with a family medical history of genetic disease.
—Couples from ethnic or racial groups at high risk for genetic disease.

### Some Counseling Suggestions

1. Involve both parents in your discussions.
2. Obtain personal and family history of patient and spouse with regard to genetic abnormality.
3. Advise patients of probabilities regarding age-related abnormalities.
4. Advise patients as to the availability of diagnostic tests, such as chromosomal analysis and amniocentesis. Discuss the nature of the information to be obtained, the procedure, and the risks.
5. Thoroughly discuss all test results with patients, making sure they understand the implications of the findings (i.e. the specific **probabilities** of genetic abnormality).
6. In cases where increased risk is a factor, make patients aware of the available options, including the abortion of the fetus, and/or techniques for avoiding future pregnancies.
7. The parents should be made aware that the final decision to become pregnant or to have an abortion rests with them.
8. Document all visits and conversations, noting matters discussed, information provided, and any decisions reached.
9. Never abandon a patient. If a conflict arises whereby the physician wishes to dissolve the relationship with his patient, he should refer the patient to other physicians and allow that patient reasonable time to select another doctor.

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**AVAILABLE ONLY ON PRESCRIPTION**
**Brief Summary**
**INDICATION:** Tenuate and Tenuate Dospan are indicated in the management of exogenous obesity as a short-term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class should be measured against possible risk factors inherent in their use such as those described below.
**CONTRAINDICATIONS:** Advanced arteriosclerosis, hyperthyroidism, known hypersensitivity, or idiosyncrasy to the sympathomimetic amines, glaucoma. Agitated states. Patients with a history of drug abuse. During or within 14 days following the administration of monoamine oxidase inhibitors, (hypertensive crises may result).
**WARNINGS:** If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly. *Drug Dependence:* Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of abuse should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with varying degrees of psychologic dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. *Use in Pregnancy:* Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential risks. *Use in Children:* Tenuate is not recommended for use in children under 12 years of age.
**PRECAUTIONS:** Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hypertension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of guanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.
**ADVERSE REACTIONS:** *Cardiovascular:* Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. *Central Nervous System:* Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache; rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. *Gastrointestinal:* Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic:* Urticaria, rash, ecchymosis, erythema. *Endocrine:* Impotence, changes in libido, gynecomastia, menstrual upset. *Hematopoietic System:* Bone marrow depression, agranulocytosis, leukopenia. *Miscellaneous:* A variety of miscellaneous adverse reactions has been reported by physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.
**DOSAGE AND ADMINISTRATION:** Tenuate (diethylpropion hydrochloride): One 25 mg. tablet three times daily, one hour before meals, and in midevening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release: One 75 mg. tablet daily, swallowed whole, in midmorning. Tenuate is not recommended for use in children under 12 years of age.
**OVERDOSAGE:** Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phentolamine (Regitine*) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

Product Information as of April, 1976

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**References:** 1. Citations available on request—Medical Research Department, MERRELL RESEARCH CENTER, MERRELL-NATIONAL LABORATORIES, Cincinnati, Ohio 45215. 2. Hoekenga, M.T., O'Dillon, R.H., and Leyland, H.M.: A Comprehensive Review of Diethylpropion Hydrochloride. International Symposium on Central Mechanisms of Anorectic Drugs, Florence, Italy, Jan. 20-21, 1977.

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8-3921 (Y587A)

# Month in Washington

President Carter has given the Congress a detailed preview of a national health insurance (NHI) proposal that would require all businesses to provide workers comprehensive private health insurance meeting federal standards. Catastrophic coverage would be mandated and the cost would be partially borne by the federal government.

The first phase of the program would cost about $15 billion. By contrast the Labor-Kennedy Bill has a price tag of from $30 billion to $40 billion; and the third major NHI plan—the catastrophic only approach—has an estimated cost of $5 billion to $10 billion.

The Administration rushed its measure out after months of tinkering and plotting in order to meet previously scheduled hearings of the Senate Finance Committee on NHI and hospital cost containment. Chairman Russell Long (D-LA) has threatened speedy action on his favorite catastrophic plan.

The American Medical Association believes, "the Administration appears to offer expanded benefits on one hand while restricting the availability of services and resources on the other."

It believes, "arbitrary government controls don't reduce costs—they simply reduce care available without addressing the public's demand and need for health care."

On the other hand, the program, "Does address major issues with which we have been concerned. For example, the AMA has supported expanded catastrophic and basic insurance coverage in the private sector, the filling of insurance gaps created during periods when insurance is not available through an employer, and more equity and uniformity within the Medicare and Medicaid programs."

The Administration measure is structured in such a way that Congress would have to approve each succeeding stage of implementation of the program, whereas the Kennedy-Labor NHI bill would have the stages automatically phased-in by law. This is the major difference between the two approaches and the principal reason for the rift between the President and Kennedy on NHI.

The President's plan provides catastrophic coverage for workers for out-of-pocket expenses above $2,500, increased federal control of Medicaid and Medicare, and complete coverage of all prenatal and birth costs.

Rep. Charles Rangel (D-N.Y.), Chairman of the House Ways and Means Health Subcommittee, said he told President Carter he would sponsor the measure when it reaches bill form.

A mandatory fee schedule will be proposed by setting a standard fee at the Medicare average in states or sub-state areas and then raising substandard Medicaid fees in those areas to that level over time. Physicians could not charge—or be reimbursed—above the fees established in the schedule. A process of negotiation would be established for subsequent fee schedule changes.

On the private side, the names of physicians who are willing to adhere to the schedule will be published in order to increase consumer choice. "A Commission will be established to look at reimbursement questions and to advise whether more stringent measures are necessary to hold down health costs and increase physician participation in the public programs."

Medicaid would be expanded and made more uniform, and a more liberal income requirement for Medicaid eligibility would be established, bringing many more people into the program, all at major new federal cost.

The most controversial features of the Administration proposal from the standpoint of health providers will be the many control features that bristle throughout the proposal.

The mandatory hospital cost containment measure is included as a provision of the NHI plan as well as in the separate measure now hung up in Congress, giving lawmakers the option of approving it in either form.

However, it is reported that the Administration is veering toward a relatively more simple plan that in its beginning stages would be mostly confined to the provision of catastrophic health benefits.

By thus jettisoning a big chunk of the President's proposed first stage NHI, the Administration would move closer to that of Sen. Long whose proposal has some chance of Congressional approval.

The Administration is said to be willing to settle for the controls embodied in the Hospital Cost Containment Act and abandon the physician fee and other controls in the plan originally outlined by President Carter.

Long is trying to hammer out a consensus bill and has indicated he is willing to go along with the Administration on the hospital measure. The Senator said he's not sure the nation can afford more than a catastrophic benefit, but said there might be room for added coverage for poor people.

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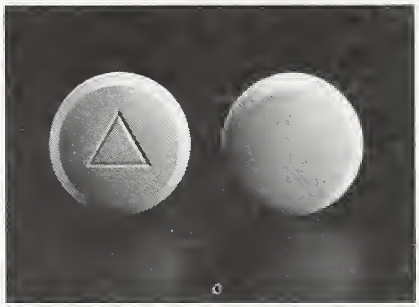
*Prepared by the Washington, D.C.*
*Office of the American Medical Association*

# The Maker

## Examining a Few Myths About Prescribing.



Increasing pressure is being put on the practicing physician to prescribe drugs generically. You are told that brand-name products are universally "expensive" and generic versions are relatively "cheap." To make this case, the most extreme (rather than typical) price differentials are cited. Thus, consumers are led to believe that such differentials are commonplace. Even your knowledge and your motives as a physician are questioned.

Understandably, these views have created myths. We think it's time to examine them in the light of all the facts and ramifications.

*MYTH: There are no differences in quality and performance between brand-name products and their generic counterparts. The corollary is that there are no differences among products made by high-technology, quality-conscious, research-based companies and those made by commodity-type suppliers.*

**FACT: The Food and Drug Administration does a good job in monitoring a generally excellent drug supply. Still, it has nowhere near the resources to guarantee the quality and bioavailability of all marketed products at any given time. Just a few months ago, for example, it noted that batches of tetracycline HCl capsules which met official monograph requirements were not bioequivalent to a reference product. As you know, there is substantial literature on this subject affecting many drugs, including such antibiotics as tetracycline and erythromycin. The record on drug recalls and court actions affirms strongly that there are differences among pharmaceutical companies and their products. Research-intensive companies have far better records than those that do no research and may practice minimum quality assurance.**

*MYTH: Industry favors only "expensive" brand names and denigrates all generics.*

**FACT: PMA companies make 90 to 95 percent of the drug supply, including, therefore, most of the generics. Drug nomenclature is not the important point; it's the competence of the manufacturer and the integrity of the product that count.**

# Matters.

*MYTH: Generic options almost always exist.*

**FACT: About 55 percent of prescription drug expenditure is for single-source drugs. This means, of course, that for only 45 percent of such expenditure, is a generic prescribing option available.**

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*MYTH: Generic prescriptions are filled with inexpensive generics, thus saving consumers large sums of money.*

**FACT: Market data show that you invariably prescribe—and pharmacists dispense—both brand and generically labeled products from known and trusted sources, in the best interest of patients. In most cases the patient receives a proven brand product. Savings from voluntary or mandated generic prescribing are grossly exaggerated.**

*MYTH: Drugs account for a major portion of the rise in health care costs.*

**FACT: Drugs represent a very small part of such costs. The amount of the health care dollar spent for prescription drugs was about 12 cents in 1967; today it is about 8 cents. And you as a physician are most conscious of how drug therapy can cut hospitalization, avert surgery, reduce office visits and keep patients on the job.**

---

*MYTH: Government intrusions into the marketplace will save tax money.*

**FACT: Government schemes always cost the taxpayer something, and the costs often exceed the benefits. Certainly, any federal "help," such as lists of wholesale drug prices sent to all physicians and pharmacists, will be no exception. Just think of the expense of keeping them current! Moreover, wholesale prices are poor guides to actual transaction prices and even worse guides to retail prices.**

## The PMA Position

We believe your freedom to prescribe, either by generic or brand name, should be totally unabridged. Otherwise, your prescribing prerogatives and your relationships with patients will be seriously impaired.

## The maker does matter

After the myths about price and equivalency have been shattered, one fact stands out more clearly than ever: *The maker does matter.* As always, your best guide to drug therapy for your patients is to select products—both brands and generics—from manufacturers with credentials and performance records you have come to respect.

PMA

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Sen. Kennedy appeared before the Finance Committee, saying "we want to work with you. There is very keen desire . . . there is no pride of authorship." He said he is willing to compromise. Despite the conciliatory atmosphere, Kennedy didn't suggest where he might be willing to compromise. He has said he's opposed to a simple catastrophic plan and opposed to any plan that calls for a first step NHI only.

Kennedy said he could support any plan that would provide cost controls, equal treatment of the population, competition within the medical system and needed reforms.

Long said the sense of Congress must be gauged on the issue of cost controls and additional medical care. "I just want to see us get together and pass the best bill that the House and Senate will accept."

The Senator has made it clear, though, that he will stick to his long-held position favoring catastrophic despite the Administration's much more extensive program, and has given no indication that he is prepared to make significant compromises.

At the same time, the lawmaker, who wields great influence in the Senate, said, "I don't think the nation can afford—nor does it want—womb-to-tomb health insurance coverage. Referring to the Kennedy-Labor Bill, though not by name, he said a single package comprehensive NHI would bind future budgets and future Administrations "to what may be inappropriate or unaffordable expenses for health insurance."

* * * *

Two key health lawmakers have issued a detailed critique of the Administration's Hospital Cost Bill contending it "would have virtually no impact on the overall rate of inflation."

The controversial proposal is still tettering in three of the four jurisdictional committees of the Congress, the Senate Labor and Human Resources having passed it earlier.

Reps. Phil Gramm (D-TX) and Dave Stockman (D-MI) said the rise in hospital costs, while continuous, is nowhere near as high as the Administration suggests in its arguments for the cap proposal.

The two members of the House Commerce Health Subcommittee said in the nine states that now have mandatory control programs (which are cited by HEW as examples of how mandatory programs can work), there has been very little impact on hospital costs.

In a 78-page detailed analysis of the plan, they said the Administration's estimated savings of $53.4 billion "is either wildly overstated, or it implies that HEW intends to severely cut the service capacity of those hospitals unlucky enough to fall under mandatory controls."

The Administration's contention that hospitals can prevent bankruptcy under this legislation is completely unsupported by the evidence, they declared.

The report shows that while costs are rising, actual out-of-pocket expenditures for health and hospital care by the American people when adjusted for inflation have remained constant for decades.

According to the representatives, the real reason for the rise in costs is the "tremendous growth" in hospital insurance coverage that pays first-dollar costs, but provides little real protection for serious illness.

Rep. Gramm said the HEW proposal "would add to the massive burden of paperwork and red tape now facing the nation's hospitals, 'ration' the quality and availability of hospital care without significantly reducing costs, and subject the health care industry to the 'whims of HEW.' "

* * * *

Overly stringent Food and Drug Administration regulations and delay are unduly retarding approval of new drugs and discouraging investigators from developing them, the AMA has told Congress.

"We do not believe at this time the benefits derived from FDA's current safety and efficacy procedures and conservatism exceed the detriments that are caused by the lack of availability of new drugs in the U.S." said Ray Gifford, M.D., a member of the AMA's Council on Drugs and head of the Department of Hypertension and Nephrology at the Cleveland Clinic.

Dr. Gifford told a House Science Subcommittee that in recent years physicians have noticed "a disturbing trend that drugs ultimately approved in this country as major treatment break-throughs have been available in other countries for significant periods of time prior to U.S. marketing."

A complete list of drugs that were marketed earlier in foreign countries include important drugs that could have made significant improvements in therapeutics had they been available earlier in the United States, Dr. Gifford said.

"Two of the most potent diuretics we now have, ethacrynic acid and furosemide, were marketed in Europe fully two years before American physicians had access to them," Dr. Gifford said. "They are the only diuretics that are effective for patients with impairment of kidney function."

He noted that in 1963 he published the results of an investigation of a new drug, bethanidine, confirming the findings of European and Australian investigators that it has a potent and useful drug. Bethanidine was approved in the United Kingdom in 1963. Subsequently, it has become available in every other country in the world (including Canada), except the United States! "This had led to the situation where I can prescribe bethanidine for my Canadian patients and not for my American patients."

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# EDITORIAL

## Cost Containment in the Boondocks

The "OK Phrase" for more than two years has been *Cost Containment* and there is probably no medical facility in the country (with the interesting exception of Oral Roberts' prospective medical palace) that has not felt the pressure of this effort.

In the past months, reading national pronouncements from HEW and from AHA and AMA, and editorials from such disparate publications as *The Wall Street Journal* and *The New Republic,* I have had a growing feeling that the very phrase "cost containment" has been throwing us off.

If we talk about shortening hospital stays, doing fewer laboratory or X-ray procedures, or admitting fewer patients to the hospital, we have not actually touched upon cost at all. Not until we actually buy fewer supplies or eliminate personnel (by reducing bed capacity for example) have we begun to affect costs. And when a work force reduction is actually accomplished, what anxieties and anguish ensue! We are going through our trial by fire at my hospital right now as we try to resolve the demand for lowered costs with the pressure for job stability.

It is obvious that the cost of medical care is a problem of many aspects, but it seems to me that the hospitals have born far more than their share of the pressure of this effort. Quite understandably, the leaders of medicine have turned their attention in this direction, primarily because hospitals are there, high profile, accessible, and manageable. I suspect, too, that a good loud program of cost containment aimed at hospitals may help drown out any faint queries about private practice and extravagant demands on medical resources, or unreasonable fees and charges.

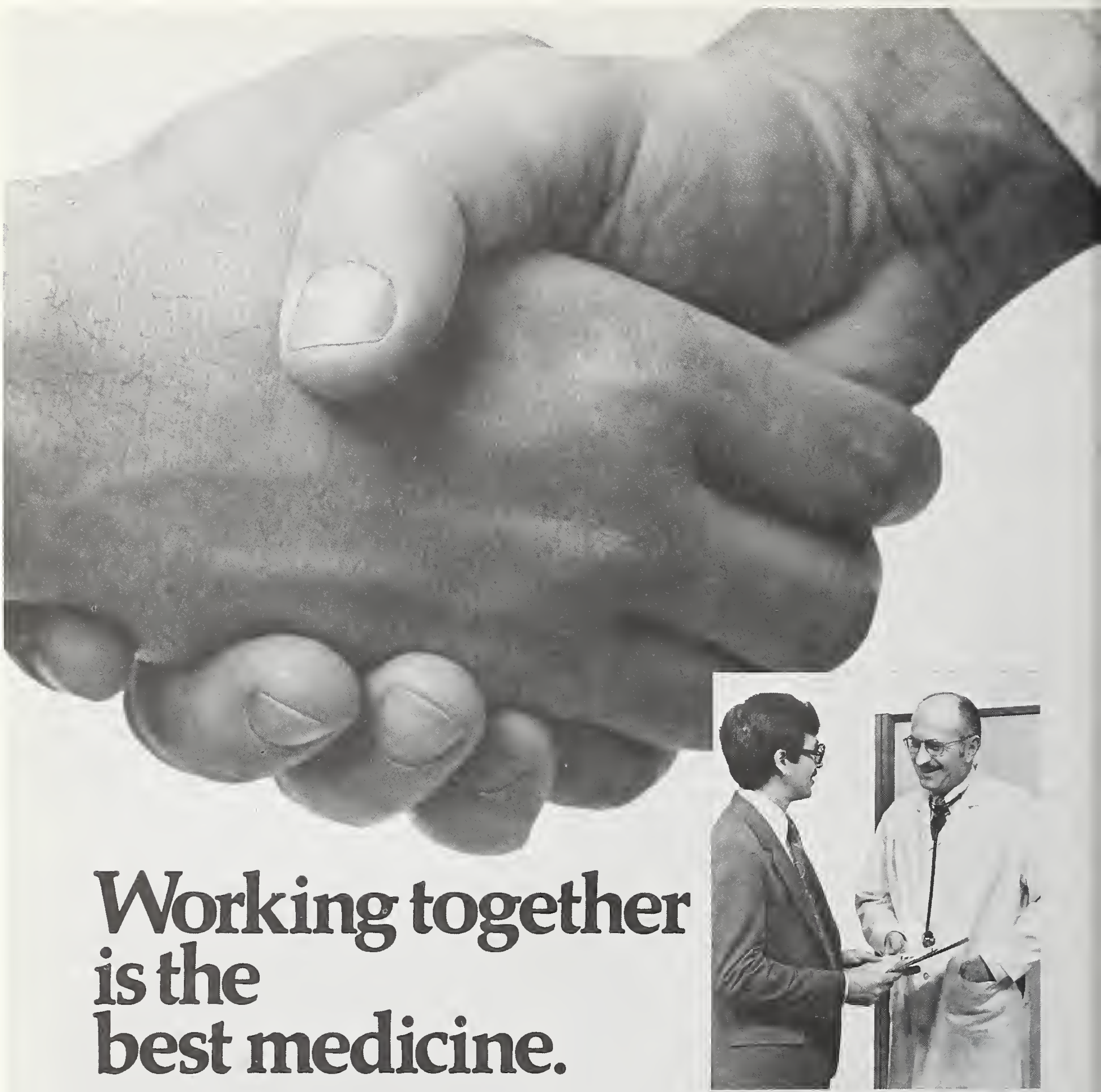
When all the rhetoric has been stripped away, it will be evident that cost containment, no matter where in the field of medical care, means reduction in either quality or quantity of medical care. In the hospitals, once waste has been reduced to a minimum (and that effort should include non-clinical and non-custodial activities of the hospital) the next reduction must be in substance. It does no good to eliminate surgical procedures if the same O.R. crew is on hand and the same overhead is necessary to keep the O.R. open. The costs are still there and have to be distributed differently. Only when beds or O.R. facilities are trimmed can we truly say we have cut costs since we have cut employment time and supply expenses.

In this respect, the small hospitals enjoy a special disadvantage, for cutting a portion of a job position is sometimes impossible. Job security is recognized as important, and the Feds have indicated that their cost constraints will allow a pass-through on escalation of wages for inflation. With fuel and supplies skyrocketing, we have precious little left to cut.

Which brings me to an urgent point: I have heard not one solitary word at any level of our national cost containment effort about bringing manufacturers and medical suppliers onto the carpet—not one word, that is, about what it *costs* to maintain our medical response.

Some of the equipment and supplies we use in our laboratory, as an example, have gone up as much as five-fold in the last two decades. Our microscopes are roughly four times as high as when I assumed my role as laboratory director in 1960. A more humble example is a new bulb for our slide projector, which cost 36% more in a few months than the bulb it is replacing.

New instruments have grown in sophistication, to be sure, but this accelerates obsolescence of the expensive equipment we already own. New price lists arrive each week with relentlessly bad news, while we stare gloomily at a 7% cap.



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And so it goes. We feel we should provide our community with up-to-date medical care and the community quite properly demands it, but insists through its official agencies that it should cost less. How can we resolve these conflicting demands?

Perhaps if the equation can be brought into focus, we can join our fellow citizens in a reasonable and broad-based approach to the problem. Demand must be realistic. Life styles may have to be altered (much expensive disability is man-made). I wish I could say I am optimistic about achieving a civilized exchange between the public, the politicians and the medical profession. I am not.

John L. Meyer, II, M.D.

# Letters to the Editor

**Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.**

## THE DOCTOR AND THE HUMANITIES

*To the Editor:* The recent contributions to the President's Page of *Connecticut Medicine* show much thought and preparation. They also indicate the concern of our Society's president for the place of physicians in the present and the future as our profession is being used as a target for the mud slingers of the media and the government. In a more recent issue of the Journal, we have been reminded that there is a weakness in the medical profession which may not be apparent to many of our colleagues.

Whether in the surgical pavilions or the hallowed chambers of grand rounds, we have become somewhat enchanted by the superb technician or the divinely inspired scientist who dispenses his conclusions with oracular wisdom. We yearn for the Oliver Wendell Holmes or the William Osler who imparted their knowledge with a flair that was established in a background encompassing the humanities, and in the case of Holmes, a legal expertise that was universally acclaimed. Although this type of physician is a rare vintage, we should attempt to encourage the young men and women with a taste for the arts as well as the sciences to seriously consider the medical profession.

In his Reflections from the Dean's Office, Dr. Massey has frequently discussed the problem encountered by medical school admissions committees in making their final selection. He states that the student begins a lifetime of medical learning in September of the freshman year but the faculty can only help if the real beginning of learning has already taken place.

Dr. Freedman tells us that the State Society is taking the first hesitant steps with the problems of the weakness of our profession in the non-scientific area. The concerns of Dr. Massey and Dr. Freedman raise some interesting questions. As a member of the State Society and president of its ear, nose and throat section, I am vitally interested in what steps are being taken and who is involved in the process. We know that we are not dealing with a local problem since Harvard University is known to be reviewing its requirements because of the decline in the students pre-college preparation especially in language. Callan has commented in J.A.M.A. relating to the poor grounding of students in the humanistic arts and social sciences.

The beginnings of medical education in this country were primarily the responsibility and administrations of the clergy. Theological control of the professional schools, especially medicine, continued for many years. For a period of several decades, proprietary schools were established and existed primarily for profit. The involved physicians, for many years, resisted efforts to close this flourishing and profitable enterprise. In the past century, primarily through private endeavor, our medical schools have become recognized and accepted as the finest in the world. However, in the process of this development, there is a concern by many that we have lost the sense of compassion that once identified the physician of the past. Perhaps a re-evaluation of our present system and a restructuring of our programs is now in order.

I believe that there are several questions which need to be answered:

1. Will the physicians themselves be interested in contributing to a solution of our present dilemma?
2. Will the colleges look to the student, not just as a scientific superstar, but as a well-rounded individual with the capacity of understanding the gift of expression and a love for the humanities as well as the ability to absorb scientific information?
3. Will the medical schools make a concerted effort to seek out such applicants and assign a definite and equitable number of points for his interest and proficiency in the arts? This should not be done on the basis of tokenism.

Timothy L. Curran, M.D.

*President, Ear, Nose and Throat Associates of Hartford, P.C.*

## RUBELLA (HIA) TITERS IN ADOLESCENT FEMALE STUDENTS

*To the Editor:* It may be of interest to physicians in Connecticut involved in the care of the school child, particularly the female adolescent, to learn about a study just completed on the incidence of serologic negative (HIA) Rubella blood tests obtained on a group of these children in the New Milford School District.

Four hundred and eighty-four children in Grades 6-12 (45% of the total female population in these grades) volunteered to have their blood taken for Rubella HIA tests. Forty-six of these children had a negative HIA titer and an additional 13 children had an HIA titer of 1:8 so that there was an approximate 12.2% incidence of young women unprotected against Rubella.

Based on information obtained from the Health Statistic Demographic Section of the Connecticut State Health Department, there is a total of 245,300 children in public and private schools and in institutions and 209,000 children in the public schools of our state, age 11-18.

If our pilot study can be used as a basis of reference, one can postulate that there are approximately 25,000-30,000 young females who are susceptible to the Rubella virus in Connecticut. A recent editorial in *Lancet* (June 23, 1979, Volume 1, No. 8130, Pages 1329-1331) states, "Only about 70% of United States children have been vaccinated and there has lately been a striking increase in the evidence of Rubella among adolescents and young adults."

May I suggest that studies similar to ours be undertaken by school health physicians and school health committees of the Boards of Education in the State of Connecticut to identify this type child?

We are indebted to Mr. John Redys of the Connecticut State Laboratory as well as the various members of the New Milford Board of Education and health personnel of our community in helping us obtain this valuable public health information.

Noah Barysh, M.D.

Danbury, CT

# WORKING FOR ALL....

This year is a very special one because it marks the 50th anniversary* of the first prepaid hospital plan in the country — the forerunner of the Blue Cross and Blue Shield concept as it is known today.

In Connecticut, the Blue Cross and Blue Shield Plans are not quite that old, but their work — for many years independent of each other, and today working as one — have always had a twofold purpose:

- To provide financial peace of mind to those in need of health care services.
- To attempt to instill good health habits in everyone — member or not.

**In 1929, J.F. Kimball, executive vice president of Baylor University, initiated the principle of health cost coverage.*

*While modest in scope and limited to only one group of subscribers, the fundamental soundness of the idea, together with the work of thousands of dedicated people, ultimately enabled tens of millions of Americans to achieve protection from the costs of illness and accidents.*

*Here in Connecticut, a plan for hospital care was incorporated in September 1936, with the first group enrolled six months later.*

*In December 1948, Connecticut Medical Service (CMS) was created for the purpose of establishing a non-profit medical/surgical service plan.*

*And on August 1, 1977, Connecticut Blue Cross and CMS began consolidating their efforts to more efficiently provide broader health care coverage.*

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# The President's Page

## CME: The "Megabuck" Industry

No profession is more dedicated to the continuing education of its members than is ours.

Medical student selection today is a complex process with many criteria considered and different schools emphasizing certain qualities more than others. Candidates must obviously have demonstrated special academic skills that would qualify them to practice medicine, and in addition most admissions committees look for evidence of an inquisitive nature and for an inclination toward the pursuit of knowledge. Selected students are then trained in an atmosphere oriented towards the evaluation of ever-changing knowledge and its implementation.

The residency training system which is unique to our profession continues and expands the utilization of knowledge obtained from a variety of sources and applies it to situations relevant to patient care.

As one progresses through years of practice, the daily pressures for learning may become somewhat lessened but love of learning and the inherent curiosity that first brought us to this profession usually does not abate for most of us. Furthermore, we are indeed fortunate that we can practice in a society and an atmosphere that encourages this natural bent for the continual acquisition of knowledge.

Although other professions may have some of the same stimuli for continuing education as we do, not many have access to the wide variety of sources such as libraries, journals, tapes, and visual aids as we find concentrated in our hospitals; nor are they as exposed to conferences, rounds and review committees to which we have voluntarily subjected ourselves. Above all, none have the peer review mechanisms which were developed and refined by the medical profession. The importance of all of this to most of us is rather obvious. We bear an awesome responsibility because we deal with matters affecting life and death.

Strange then how a multimillion dollar "industry" has apparently emerged from such an altruistic concept. It would appear that the usual sources of information are no longer satisfactory in these stressful times and acquisition of knowledge can best be accomplished in more exotic surroundings such as Caribbean cruises and African safaris. We have permitted ourselves to be seduced by the Airline and Travel industries to an extent that has perverted our noblest motives. Even universities have permitted the development of massive programs of continuing education some of which in reality are no more than a means of replacing lost government funding for other projects.

To permit the growth of CME into a "megabuck" industry is nothing more than crass commercialism.

We have a responsibility to our profession and our patients to keep abreast of current knowledge. We should also document to our satisfaction our performance in the execution of this responsibility. Above all, however, we must protect our time-honored concept of never ending education from becoming a pawn in the hands of "megabuck" entrepreneurs.

Edward A. Kamens, M.D.
*President*

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**INDICATIONS:** *Therapeutically,* (as an adjunct to systemic therapy when indicated), for topical infections, primary or secondary, due to susceptible organisms, as in: infected burns, skin grafts, surgical incisions, otitis externa; primary pyodermas (impetigo, ecthyma, sycosis vulgaris, paronychia); secondarily infected dermatoses (eczema, herpes, and seborrheic dermatitis); traumatic lesions, inflamed or suppurating as a result of bacterial infection. *Prophylactically,* the ointment may be used to prevent bacterial contamination in burns, skin grafts, incisions, and other clean lesions. For abrasions, minor cuts and wounds accidentally incurred, its use may prevent the development of infection and permit wound healing.

**CONTRAINDICATIONS:** This product is contraindicated in those individuals who have shown hypersensitivity to any of its components. Do not use in the eyes or in the external ear canal if the eardrum is perforated.

**WARNING:** Because of the potential hazard of nephrotoxicity and ototoxicity due to neomycin, care should be exercised when using this product in treating extensive burns, trophic ulceration and other extensive conditions where absorption of neomycin is possible. In burns where more than 20 percent of the body surface is affected, especially if the patient has impaired renal function or is receiving other aminoglycoside antibiotics concurrently, not more than one application a day is recommended.

When using neomycin-containing products to control secondary infection in the chronic dermatoses, it should be borne in mind that the skin is more liable to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for that patient thereafter.

**PRECAUTIONS:** As with other antibacterial preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs.

**ADVERSE REACTIONS:** Neomycin is a not uncommon cutaneous sensitizer. Articles in the current literature indicate an increase in the prevalence of persons allergic to neomycin. Ototoxicity and nephrotoxicity have been reported (see Warning section).

Complete literature available on request from Professional Services Dept. PML.

# Reflections from the Dean's Office

## Summer Reading

ROBERT U. MASSEY, M.D.

"If one cannot drive, one can read," wrote David Broder in his column last month. Being set free from the tyranny of the automobile for some of our days does give us time for other pleasures and pastimes.

Summer is an especially good time for reading, and although reading while loafing needs no purpose beyond the mere pleasure of it, I suspect one could say that it is as beneficial to health as jogging, there being no data to support the efficacy of either. For physicians I recommend medical history.

Oswei Temkin, former director of the Institute for the History of Medicine at The Johns Hopkins University, makes a distinction between the *past*, "everything that happened," and *history*, "the past organized into a tale." He designates the serious study of history, including research and explanation, as *historiography*." For those of us who are busy with practice and trying to improve our art and science, history as the "past organized into a tale" is enough, especially if it is a good tale. Serious scholarship might come later, but it doesn't have to.

In anxious times of rapid change and gasoline shortages, the longer view which history provides can have a settling effect, and may even add wisdom to the business of making sense of the morning newspaper. No one reads history deliberately to gain new perspectives or some grand world view. History interests us because it is, if artfully written, a good tale, often a tale of people we have known, of places and times in which we have lived, and of scenes in which we may have played some part.

Medical history and history of science are again respectable academic disciplines. The number of serious scholars in these fields has increased tenfold in the past decade. If this is anything more than a passing academic fancy, it could signal something momentous in our western culture. One of the discoveries of the Renaissance was that Europe had had a past; only in this century have we been producing graduates who, like students in the twelfth century, are unaware of any time before their own.

Because the present moves on with such speed, even the recent past is soon forgotten. Benson and McCallie[2] recently reviewed five treatments for angina pectoris which had been advocated with enthusiasm during the past fifty years, and then abandoned. With each new treatment, 80 percent of the patients were improved, but that percentage fell rapidly with subsequent trials, until now all of these treatments have been abandoned. Three of the treatments were drugs: xanthines, khellin and vitamin E; two were surgical procedures: ligation of the internal mammary artery and implantation of the internal mammary artery. Without adding a single new "fact", this bit of medical history helps to put coronary artery bypass in a context where it assumes a new meaning, much like putting a word in a sentence.

These new insights are useful and momentarily exciting; they are not the chief reason for reading medical history for those of us who will never become medical historiographers. There need be no other justification than the pleasure which may attach to any harmless avocation.

For me a vertical approach to reading history is more satisfying than a horizontal one: one century, one person, or one disease at a time. The seventeenth century is good to start with; it is that part of the late Renaissance when science was getting underway, and it is a good century from which to launch into the Middle Ages or even into classical times. Chauvois' *William Harvey*[3] is shorter and easier to read than Geoffrey Keynes' biography, but for an introduction into the way a seventeenth century physician might solve a biological problem, Harvey's *De Motu Cordis* is preeminent and can be read in a weekend. For an understanding of how a classically educated young physician from the same time thought about religion and philosophy, Thomas Browne's *Religio Medici* makes another weekend project. Together they are a fair excursion to that great century, and the commentaries on Browne and Harvey which are available in any good medical library could easily usurp all leisure reading for a year.

For some this will all seem to be dullness and irrelevancy. But for others a door might open into a new room whose fascinating crannies can be explored without using much money or gasoline. If you are a Dorothy Sayres fan, you may remember that Lord Peter Wimsey carried Browne's *Religio Medici* in his inside coat pocket. That would be ideal for gasoline lines.

---

ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

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# Further Reflections on the Saikewicz Decision

JOSEPH M. HEALEY, J.D.

The *Quinlan*[1] and *Saikewicz*[2] cases represent the efforts of two Supreme Courts to address the problems involved in deciding to withhold life-prolonging treatment from an incompetent patient. Under the Quinlan case, the decision of a guardian and physician, to withhold treatment, would be reviewed by a prognosis committee, and decisions made in this manner would be legally protected. As long as appropriate committee process was followed, the parties would be immune from prosecution. The *Saikewicz* case is more complex. Under it, a non-judicial committee like a prognosis committee would have no legal authority to grant immunity from liability. That authority would be reserved to the judiciary. What is not perfectly clear is which cases must be presented to the courts for their review. Attempts to ascertain the answer to this question have not been entirely successful. The case of *In the Matter of Shirley Dinnerstein*[3] represents a major step toward clarification. An understanding of this case is important to an understanding of this area of the law and to subsequent Connecticut attempts to formulate policy in this area.

At the outset it should be pointed out that the *Dinnerstein* case was decided by the Appeals Court of Massachusetts. The decision was not appealed to the State Supreme Court which had decided the *Saikewicz* case. As such, it is not a pronouncement of the highest court of the state on these issues. Nonetheless, it is helpful in assessing the true meaning of the *Saikewicz* case and its implications for the medical profession.

Shirley Dinnerstein was a 67-year-old woman suffering from a disease of the brain called Alzheimer's disease. It is a progressive and unremitting degenerative disease which results in disorientation, loss of memory, personality disorganization, loss of intellectual function and loss of all motor function. There existed at the time neither cure for the disease nor treatment to slow or arrest its course. Ms. Dinnerstein had also suffered a stroke. She was confined to a hospital bed in an essentially vegetative state: immobile, speechless, unable to swallow without choking, and barely able to cough. Her son who was a physician, and her daughter, both agreed with the attending physician that her condition was hopeless. They also agreed that if cardiac or respiratory arrest were to occur, that no resuscitation efforts would be undertaken. The family, the attending physician and the hospital joined in filing a suit to determine whether such a decision requires the prior approval of the court.

In its decision, the Appeals Court pointed out its belief that the *Saikewicz* opinion did not require that cases like Ms. Dinnerstein's be presented to the court. Of particular significance to them, was the absence of any treatment capable of curing or relieving the illness which would have brought the patient to the threshold of death. In the *Saikewicz* case, treatment for the patient's leukemia was available, though it was ultimately rejected. The Appeals Court regarded Ms. Dinnerstein's case as presenting questions which were within the competence of the medical profession, namely:

> "what measures are appropriate to ease the imminent passing of an irreversibly, terminally ill patient in light of the patient's history and condition and the wishes of her family."[4]

The case was sent back to the Probate Court with instructions that the law did not prohibit in this case a course of medical treatment which excludes attempts at resuscitation in the event of cardiac or respiratory arrest and that the validity of an order to that effect did not depend on prior judicial approval.

Those in Connecticut who wish to start thinking about the development of an appropriate mechanism in this state need to read carefully the decisions in these cases and the abundant literature now available.[5] Of particular importance will be the selection of the review mechanism, the process of granting immunity from liability and the determination of which cases must be subject to the review mechanism. There is need for much planning and careful reflection.

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JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington.

# In Memoriam

**GOLDYS, FRANK M.,** Tufts College, 1926. Dr. Goldys was a general practitioner in Fairfield since 1927. He had been the medical examiner for Danbury for many years and earlier had been medical examiner for nearby towns. He was a former chairman of the medical staff at Danbury Hospital and had also been president of the Danbury Heart Association. From 1943 to 1945 he served as a medical officer in the U.S. Army Air Corps with the rank of major. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Goldys died June 3, 1979 at the age of 78.

**HETZEL, JOSEPH L.,** Yale University School of Medicine, 1926. Dr. Hetzel was a pediatrician in the New Haven area from 1928. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Hetzel died April 30, 1979, at the age of 77.

**MORROW, HOWARD S.,** Columbia P & S, 1940. Dr. Morrow was an obstetrician-gynecologist in the Litchfield area since 1948. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society. Dr. Morrow died May 14, 1979, at the age of 63.

**PHILLIPS, KARL T.,** Tufts University, 1919. Dr. Phillips was a surgeon in the Windham area from 1921 until his retirement in 1964. For many years he served as President of the Medical Staff and Chief of the Department of Surgery at Day Kimball Hospital. He was a member of the Windham County Medical Association, the Connecticut State Medical Society and the American Hospital Association. Dr. Phillips died April 5, 1979, at the age of 84.

**SHERMAN, SAUL H.,** Columbia University, 1934. Dr Sherman was an internist in the Stamford area for forty years, During World War II he was a Major in the U.S. Army. He was a member of the Fairfield County Medical Society, and the Connecticut State Medical Society and was a past president of the Stamford Medical Society. Dr. Sherman retired to Santa Fe, New Mexico, where he died April 14, 1979, at the age of 70.

**SPIGNESI, JOHN T.,** Georgetown Medical School, 1930. He was a general practitioner in the New Haven area since 1931. Dr. Spignesi served his internship at St. Mary's Hospital in Waterbury and later became contract surgeon for the Civilian Conservation Corps in Clinton. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Spignesi died May 1, 1979, at the age of 73.

**WHEELER, MAYNARD C.,** Columbia College of Physicians and Surgeons, 1929. Dr. Wheeler was an ophthalmologist in the New Haven area since 1935 until his retirement in 1975. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Wheeler died April 24, 1979, at the age of 76.

## BOOK REVIEW

**Dr. William W. Herrick: A Measure Of The Man. Letters, Addresses, and Tributes Collected By His Daughter Eunice Herrick Trowbridge For Family And Friends.** Copyright 1978 by Eunice Herrick Trowbridge. 72 pages, illustrated. (Available from the author, 70 Brookside Road, New Britain, CT 06052: $12.50.)

William W. Herrick was one of the renowned physicians of the generation spanning the end of the 19th Century and the early part of the modern era. He, more than most, helped usher in the changes which have evolved into medical practice as we now know it. While maintaining a private practice of internal medicine in New York he simultaneously held an appointment as Professor of Clinical Medicine at the College of Physicians and Surgeons of Columbia University. At the culmination of his professional career, shortly before his death in 1945, he served as President of the New York Academy of Medicine.

His connections with Connecticut were many. He was born in 1879 to parents who had met while his father was studying at Yale Divinity School, and the family lived in Middle Haddam, Sherman, and Gaylordsville. William W. Herrick graduated from Yale College and in 1905 from the School of Medicine. Although his practice was based in New York City, he maintained a home in Sharon, Connecticut, and was a strong influence in the social and medical life of this community and its hospital.

The personal and family history of this man are told in loving detail in this memoir by his daughter. The volume is divided into sections which include family reminiscences, selected letters from Dr. Herrick revealing his personality and beliefs, and several addresses which highlight his feelings about social continuity and the role of medicine.

The descriptions of his early married life read like duplicates of those created by Edith Wharton in her depiction of upper-class New York society of the last century, particularly evident in the charming family photographs which illustrate this book. Yet while these simpler days of the past have an obvious allure to those of us bound by the constraints and anomie of modern life, we must be reminded that unpredictable disaster often lay just over the horizon. In 1877, two years before his birth, three siblings under the age of six died of diphtheria in a ten-day span. And the subject himself had his career interrupted to take the "cure" for tuberculosis: rest, fresh air, and fresh milk.

This book should be attractive to all interested in the recent history of medicine, especially that of northwestern Connecticut. There is little discussion of medicine in specific but much of the social milieu in which it was practiced. Finally, those interested in what remains of the heritage of the past will appreciate the superb example this volume affords of the almost lost arts of printing and bookbinding. Would that we all had such a memorial for our lives.

M.B. Ozonoff, M.D.

*Director of Radiology*
*Newington Children's Hospital*

# OBITUARY

## FRANCIS W. DELLIGAN, M.D.
1915-1979

Francis William Delligan was born on May 26, 1915 in Stafford Springs, Connecticut and received his early education in the local school system of that town. His father doubled as a plumber and chief of the volunteer fire department. Frank was the manager of Stafford High School football team in 1932 and graduated from there in 1933 with 45 other students. He went on to the University of Notre Dame where the freshman football team numbered almost three times as many as Frank's high school graduating class. Included in his graduating class from Notre Dame was Charles Hufnagal, who was to become one of the country's pioneers in cardiac vascular replacement surgery. After receiving his B.S. in Pharmacy, Frank continued his education at Georgetown University and he was awarded his Doctor of Medicine from that institution in 1941.

Returning to Connecticut as an intern at St. Francis Hospital in Hartford in 1941, Frank continued on at that institution as a pathology resident under the late Dr. Louis P. Hastings, one of Connecticut's first and finest pathologists. Frank then joined his former medical school professor, the late Dr. Frederick Coe, as a fellow in radiology at Georgetown University Medical School. After completing his radiology training in Washington, Frank spent a short period at the Neurological Institute of Columbia Presbyterian Hospital in New York City.

In 1945, Dr. Delligan returned to St. Francis Hospital and became the first full-time Director of Radiology. He continued as a radiologist at the hospital and spent some time in part-time private practice of radiology until his cardiac valvular disease progressed and caused his early retirement and requiring him to undergo two open heart valvular replacement surgical procedures.

Dr. Delligan was certified by the American Board of Radiology in 1947, and became a member of the American College of Radiology, the Hartford Medical Society, the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association.

Frank was a quiet, but jovial man who always enjoyed the practice of radiology. One of his outstanding qualities was his ability to befriend and treat with the utmost respect his fellow workers, including the first year student radiology technicians, all of whom worshiped him.

Frank was a devoted husband to Muriel Ruddy Delligan, whom he met during internship while she was a student nurse. They have four children: William Delligan of New York City, John R. Delligan of San Francisco, Francis W. Delligan and Mary Ellen Smith, both of West Hartford.

There is a void in our medical community with the passing of this truly fine gentleman and physician. His fellow physicians of Connecticut extend their sincere sympathy to his family on their great loss.

Richard J. Cobb, M.D.

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**Efforts to regulate** physician supply are underway in several states and similar proposals are likely to develop in other states, the AMA warned in a memorandum to constituent associations and specialty societies. In Hawaii and Rhode Island, state health planning agencies are seeking to impose certificate-of-need licensure based on predetermined estimates of the number of physicians required. In California and New York, health planners are working to limit the number of physicians by regulating residency training. The AMA memo points out that proposals to manipulate the types of physicians being trained were defeated at the federal level in 1976 during consideration of the Health Professions Education Assistance Act. Attempts by states to use the National Health Planning and Resources Development Act for this purpose are outside the scope of the law, the AMA said.—*In Brief,* A summary of AMA, Medical and Health News

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# ANNUAL REPORTS

## OF THE CONNECTICUT STATE MEDICAL SOCIETY

1978 - 1979 *(concluded)*

### Report of Delegates to AMA
### Chicago
### December 3-6, 1978

Orvan W. Hess, M.D. (D)
Andrew Canzonetti, M.D. (A)
Guy W. Van Syckle, M.D. (D)
Sidney L. Cramer, M.D. (A)
J. Alfred Fabro, M.D. (D)
William A. Whalen, Jr., M.D. (A)

The House now consists of 271 Delegates from 55 States, Territories and 50 National Specialty Societies as well as the Army, Navy, Medical Schools and Public Health Service. The Interim Meeting opened on Dec. 3 with reports by Dr. Robert Hunter, Chairman of the Board of Trustees and Dr. James Sammons, Exec. Vice-President. President Tom Nesbitt presented a most interesting address on "The Question Is" which has been published in Connecticut Medicine. He emphasized the AMA's role in the program for voluntary containment of health care costs and appealed to physicians to restrain increase in fees.

Mr. Newton Minow, the Association's outside Legal Counsel, informed the House of areas of pending litigation faced by the AMA including the new FTC rulings on physician advertising, and medical ethics. These affairs are demanding a great deal of effort and enormous financial outlay for the Association.

We were informed about the outrageous decision of the Administrative Law Judge of FTC in their standing lawsuit against the Connecticut State Medical Society, New Haven County Medical Association and the AMA concerning alleged restraint of advertising which attacks professionalism. His ruling denies any role of the AMA in setting standards of ethical practice without the "permission and approval of the FTC." We heard of other invasions by FTC in an effort to remove the AMA from the process of accreditation of medical schools. The FTC urged the U.S. Office of Education not to recertify the Liaison Commission on Medical Education as the official accrediting agency. The AMA will continue to pursue court action in connection with the FTC suit against Connecticut, continue to support the role of LCCME accreditation of continuing education by state medical associations, and seek to introduce bills in Congress to confirm the authority of the medical profession to develop and use relative value studies, which were outlawed by the FTC.

More than 200 items of business were considered at this important meeting: 40 reports of Board of Trustees, 50 reports of the Judicial Council, Council on Medical Services, Council on Medical Education and other Standing Committees plus 130 resolutions. Since reference committees meet simultaneously, it was logistically impossible to attend all of them. Nevertheless, your Connecticut Delegates and Alternate Delegates, with the assistance of President Freedman and President-Elect Kamens, did a very efficient job of monitoring and participating in the discussions.

Three major issues which were considered and debated in the House are:

A. Chiropractic and the settlement of the Pennsylvania suit brought by a chiropractor against the AMA, the Pennsylvania Medical Society, and other organizations.

B. The question of National Health Insurance and whether the AMA should cause a proposal to be introduced into Congress and, if so, what would be contained in the Bill.

C. The proposed revision of the Principles of Medical Ethics.

1. Much information has been disseminated on action taken by Chiropractors against the AMA and Medical Societies in Pennsylvania and New Jersey charging that there was a conspiracy to prevent Chiropractors from practicing their profession as provided by the law. Settlement was made by all parties except the Pennsylvania Radiological Society and the American College of Radiology. Much controversy developed with respect to the proper role of the Board of Trustees in the settlement of the litigation and the interpretation of the Principles of Ethics by the Judicial Council. The House affirmed the authority of the Board of Trustees to settle a lawsuit, in the best interest of the members and the public, in accordance with the Bylaws of the AMA and of the State.

In addition, the House adopted the following recommendation:

(a) The AMA supports the right of a physician to choose those persons who he or she will accept as patients and also to exercise his or her choice by the terms of contractual arrangements with other physicians, medical groups, hospitals or other institutions.

(b) The obligations which a physician has to provide information to a patient or any other party are those required by customary good medical practice and law.

(c) The Judicial Council be requested to reconsider Article 3.70 of Section III of Judicial Council Opinions and Reports.

(d) The AMA continue to warn the public of the hazards to health of entrusting the diagnosis and treatment of diseases such as cancer, diabetes, malignant hypertension, cardiovascular stroke, and infections to practitioners who, in the treatment of these conditions, rely upon the theory that all disease is caused by misalignment of spinal vertebrae and can be cured by manual manipulation of the spine.

(e) The authority of the AMA Board of Trustees to have agreed to the proposed settlement in the Slavek case be acknowledged and affirmed.

(f) Nothing in the above five items would be interpreted or construed as an amendment to the Principles of Medical Ethics of the AMA.

2. *National Health Insurance* and the position of the AMA was a major topic for debate. The Reference Committee considered two reports of the Board of Trustees and ten Resolutions related to this issue. Report MM of the Board of Trustees in agreement with the Council on Medical Service and the Council on Legislation called for reaffirmation of the AMA's 17 Principles for Comprehensive Health Insurance and sponsorship by the AMA in the 96th Congress of a Bill, such as 1818, based on the 17 Principles with the modification:

(a) Change the name of the Health Insurance Board to the Health Insurance Advisory Board, and change its responsibility to an advisory role.

(b) Provide for states to assume part of the premium costs of health insurance for residents who are poor.

(c) Clarify the intent that there are no changes in the physician-patient relationship, including the physician's right to bill and receive payment from patients.

(d) Include explicitly as covered benefits the services provided by an ambulatory surgical facility as well as rehabilitative services.

(e) Clarify the fact that the physician's usual, customary and reasonable charge is the basis for payment, unless other arrangements have been made by the physician with the patient or the insuror.

(f) Provide an explicit antitrust exemption for local fee review committees established by medical societies.

(g) Change the name of the bill to the Health Insurance Improvement Act of 1979.

After lengthy discussion, pro and con, before the Reference Committee and heated debate on the floor of the House, it was voted that the AMA sponsor legislation, to be presented to Congress if necessary, embodying the following principles:

(a) Requiring minimum standards of adequate benefits in all health insurance policies sold in the United States with appropriate deductible and co-insurance.

(b) A simple system of uniform benefits provided by the federal, state, and local governments for those individuals who are unfortunate enough (through no fault of their own, i.e., age, disability, financial hardship, etc.) not to be able to provide for their own medical care.

(c) A nationwide program by the private insurance industry of America (and government if necessary for reinsurance) to make available catastrophic insurance coverage for those illnesses and individuals where the economic impact of a catastrophic illness could be tragic. All catastrophic coverage should have an appropriate deductible and co-insurance to make it economically feasible and to avoid abuse.

(d) A program developed pursuant to these principles should be administered at the state level with national standardization through federal guidelines.

3. The Ad Hoc Committee on the *Principles of Medical Ethics*, established in 1978, reported that it had been unable to accomplish its mission because of several matters that had not been resolved as yet and requested it be authorized to continue its study and report at the 1979 Annual Meeting. The recommendation was accepted by the House. Attempt was made in the discussions to clarify the difference between the "Opinions and Reports of the Judicial Council" and the "AMA Principles of Medical Ethics." The former was determined to be a "basic compilation of interpretations, opinions and statements" of the AMA Judicial Council and do not represent amendments to the "Principles of Ethics" which, Dr. Tremain Bradley pointed out, must be brought before the House of Delegates. It is anticipated that the Judicial Council and Ad Hoc Committee will submit a revised Code of Ethics at the 1979 Annual Session.

4. In response to Resolutions (1978 Annual Convention) to "Recommendations of the National Commission on Cost of Health Care" calling for (a) Placement Review Criteria and (b) Regional Center for high-cost Technologies, the following Reports of the Board of Trustees, with amendments, were adopted:

(a) "The AMA supports the development of rational criteria by local planning bodies for placement of very expensive facilities and equipment. However, if national guidelines are developed to assist states and localities in this activity, such guidelines should be developed only with the cooperation of local practicing physicians and other health professionals, should be advisory, not mandatory, and should be used only as general benchmarks to assist localities in establishing their own criteria more responsive to local needs and resources."

(b) "Where opportunities for improved quality or availability of care and/or for cost savings exist, experimentation with regional centers for high cost specialized technology should be encouraged."

In a supplementary response to a National Commission recommendation on "Fair Market Health Plan Competition," the Council on Medical Service presented an excellent review on the *Status of HMOs* including *Individual Practice Associations* (IPA) with the recommendation that "the House reaffirm support of the concept of neutral public policy and fair market competition among all systems of health care delivery."

5. *Second Surgical Opinion Program.* The Council of Medical Service surveyed problem areas with the government and insurors. The House of Delegates awarded and adopted the following recommendation:

> Recognizing that the advisability of surgery or other specific therapy can be a matter of opinion, the House of Delegates of the American Medical Association (a) Reaffirms the right of a patient or a physician to seek a second opinion freely from any physician of his/her choice; (b) opposes the concept of mandatory second opinions or the imposition of financial penalties by a third party payor for not obtaining a second opinion; and (c) supports the concept that, when a second opinion is required by a third party, that second opinion should be at no cost to the patient.

6. *Cost Benefit Analysis and Decision Theory.* The trend to apply cost-benefit analysis to the delivery of patient care pervades many areas of society. In the opinion of the Judicial Council there is no way to put a price tag on a human life despite the existence of finite resources. Further scientific study of the effectiveness of varying modalities of treatment and efficient utilization of medical resources was recommended by the Reference Committee and adopted by the House.

7. The Connecticut Delegation has an outstanding record of introducing Resolutions dealing with subjects of national significance such as the establishment of a statutory Definition of Death, Reimbursement for Abortion, Due Process, Cost-Benefit Analysis, Establishment of a Central Repository of Information for Technology Assessment, Certification of Technical Assistants in operating rooms, investigations of Drug-Lag and determination of international standards of Experimentation, Physician Representation on Health Systems Agency Governing Bodies, distribution of AMA News to Non-members, Medical Staff representation on Hospital Boards of Trustees, Hospital Privileges for Podiatrists, etc. Response to several of these is to be found in Reports of the Board of Trustees or Councils to which they were referred.

Connecticut Resolutions introduced to the House at the Interim Meeting and actions taken were: (a) the ethics of in vitro fertilization of human sperm and ova, (b) guidelines for due process, (c) the AMA and leadership in bioethics, (d) study of the federally sponsored elderly health screening program. All were adopted by the House with some minor amendments.

a. *Ethics of in vitro fertilization of human sperm and ova.* The purpose of this resolution was to have the AMA adopt a policy on the ethics of this procedure. Ever since the successful birth of a child by in vitro fertilization by Steptoe and Edwards in England, there have been requests for Federal funds to finance research in this field. Public hearings were being held in the 10 HEW regions by a congressionally mandated 14-person national Ethics Advisory Board appointed by Secretary Califano, with no official representation from the AMA. Assisted by this testimony, the Board was to make a recommendation on the ethics of the procedure to Califano, who then was to decide whether Federal money would be used to support such research.

Since the AMA had no policy on the ethics of the procedure, the resolution asked the House (a) to state that such experimentation is ethical; (b) that embryo transfer of ova fertilized by sperm involving husband and wife is ethical—with their informed consent to the various medical and legal components; and that the Judicial Council, using outside consultants, study other problems involved in the procedure and report back at the next convention.

The Judicial Council, which had not made a statement to the House about in vitro human fertilization, had (apparently after submission of our resolution) submitted a statement on it to the national committee and then to the reference committee, which recommended it to the House as a substitute amendment.

From all public reports and statements of ethicists and scientists before the Ethics Advisory Board, the vital question of in vitro fertilization is: When does life begin? There was, and is, no consensus about this. If the Board ruled that life began the instant of fertilization, some would call such experimentation murder. The Judicial Council analogized the procedure to artificial insemination, completely ignoring the central problem of life.

There followed, on the floor of the House, an unusual give-and-take about the ethics involved between Dr. Dobbins, chairman of the Judicial Council, and Dr. Fabro, who finally made a motion to adopt the first two resolves of the original Connecticut resolution. The House, without a single dissent, adopted our resolution.

The issue to the House was: Who should formulate policy involving medical ethics? Should it be a congressionally mandated committee (Ethics Advisory Board) appointed by the Health, Education and Welfare Secretary with no official representation from the medical profession? Or should it be the AMA, whose House of Delegates now includes delegates elected by the national students' association, the residents, the deans of medical schools, and by each of more than 50 national specialty associations? The answer is obvious.

Since our convention in December, 1978, the Ethics Advisory Board has concluded that in vitro fertilization research and embryo transfer can be ethically acceptable—at least for the purpose of Federal financing. While Secretary Califano is not required to act on the recommendations, he is expected to do so. As to the crucial issue of when life begins, the committee is reported as stating that "no embryo will be sustained in the test tube beyond 14 days, the stage normally associated with the completion of implantation in the uterus.

(b) *Guidelines for due process:* Since our last AMA convention the Joint Committee on Accreditation of Hospitals, on which the AMA has 8 of its 22 members, the 12 or so pages in the 1971 Guidelines for due process in hospitals had been rescinded. Though these Guidelines have proved to be too detailed, legalistic, and even complex, especially for smaller hospitals, they were a great improvement over the then existing void. The new Guidelines adopted in 1978, without knowledge of or consultation with our House of Delegages, have gone to the other extreme: they are too general, short, and deal in principles. They will require amplification by individual hospitals, which probably will rely on hospital lawyers, in many cases not the optimum.

This resolution asked the House to direct the AMA legal department to draw up written guidelines amplifying into reasonable detail the principles of ethical procedural due process, as have been adopted by the AMA, but designed for hearings in whatever forum an aggrieved physician should find himself, for physicians, not lawyers.

The reference committee, however, while recommending to the House adoption of formulating such guidelines, recommended referring the task to the Judicial Council. Because the Connecticut delegation perferred that it be done by the AMA legal department, one of our delegates, again on the floor of the House, was able to persuade the House that it be referred to the legal department for presentation at our next convention.

An interesting episode occurred after the convention. Reading about the resolution in the AMA News, a physician from a Midwest community hospital called to tell of his experience. He had been suspended by his medical staff several years before and is now suing some members for defamation and loss of earnings after a judge had ruled in his suit that he:

(1) "was never given a statement of all the charges that were considered against him:

(2) was not given an opportunity to hear and cross-examine any witness, to rebut all of the evidence in his own behalf;

(3) was given insufficient notice to know what would take place and insufficient time to prepare a defense;

(4) was not informed of all the allegations which the executive committee defendants and the board of governors actually relied on in deciding to suspend his privileges;

(5) did not have the benefit of an impartial panel to hear the question of his privileges;

(6) was never provided a statement of the reasons his privileges had been suspended after the decision was made."

Our resolution is intended to prevent such occurrences. Connecticut may not need such guidelines, but, as this case demonstrates, other parts of the country do. The AMA legal department knows of no court ruling overruling a hospital decision involving privileges where procedurally ethical due process has been followed by a medical staff.

(c) *The AMA and Bioethics:* Because our delegation, shared by an increasing number of the delegates, believes the AMA has abdicated its leadership in bioethics, it introduced a resolution calling on the AMA to reaffirm its leadership in ethical issues. In 1974, Congress mandated the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to study and report to Congress and HEW on ethical problems. It has produced several major ethical reports. It is being replaced by a 14-member Ethics Advisory Board appointed by Secretary Califano to study and report on ethical problems. The AMA was not invited to appoint an official representative to either Commission. This resolution not only would reaffirm its leadership, but also request government officials for such representation.

The House adopted the resolution. A committee of the House, mandated by the House, is now studying not only a revision of the Principles of Medical Ethics suggested by the Judicial Council, but the role of the AMA and its Judicial Council in the many important societal problems involving traditional medical ethics and bioethics.

(d) *Elderly Health Screening Program:* This resolution calls for a study and recommendations to the House at its next convention about the federally mandated program.

It stems from the experience, especially of primary and family physicians, with some of their elderly patients who obtain multiphasic screening tests and limited examinations, financed by the government, results of which are sent to the physician of the patient's choice.

Many elderly patients apparently consider this a complete examination and no longer return to their regular physician. Not only is there question about the wisdom and benefit of these multiple tests, but about the legal obligations of the physician who receives these usually unsolicited reports.

The resolution is a response to the reaction of family and primary physicians. Because it deals with a Federal program (P.L. 84-73), it was felt proper that it be dealt with at the AMA level.

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## Report of the Treasurer

### Hilliard Spitz, M.D.

The financial statements prepared by Seward and Monde, auditors of the Society, are largely self-explanatory and are published herewith as the report of the Treasurer.

**Balance Sheet December 31, 1978**

| | | | Special Funds | | | | | |
|---|---|---|---|---|---|---|---|---|
| ASSETS | TOTAL | GENERAL FUND | GURDON W. RUSSELL | O. C. SMITH | BUILDING | FUNDED RESERVE FOR DEPRECIATION | CSMS AMBULATORY CARE STUDY FUND | THE CONNECTICUT HUMANITIES COUNCIL INC. GRANT FUND |
| Cash ................ | $408,341 | $323,789 | $ 475 | $ 3,290 | | $ 80,687 | $ 100 | |
| Investments - at cost (Note 2) (market value $185,666) ............ | 195,871 | 194,217 | 1,654 | | | | | |
| Note receivable (Note 3) | 4,999 | 4,999 | | | | | | |
| Dues receivable ........ | 925 | 925 | | | | | | |
| Accounts and reimbursements receivable ..... | 10,344 | 10,284 | | | | | 60 | |
| Due (to) from other funds .............. | | ( 989) | | | | | ( 160) | $ 1,149 |
| Land ................ | 12,270 | | | | $ 12,270 | | | |
| Building and building equipment (Note 1) .. | 140,172 | | | | 140,172 | | | |
| Automobile emblems on hand .............. | 245 | 245 | | | | | | |
| Prepaid expense ....... | 2,673 | 2,673 | | | | | | |
| Totals ........... | $775,840 | $536,143 | $ 2,129 | $ 3,290 | $152,442 | $ 80,687 | $ — | $ 1,149 |
| LIABILITIES | | | | | | | | |
| Accounts payable ...... | $ 59,546 | $ 59,546 | | | | | | |
| Accrued expenses payable ............... | 954 | 954 | | | | | | |
| Unexpended Connecticut Humanities Council Grant ............. | 1,149 | | | | | | | $ 1,149 |
| Fund Balance ......... | 714,191 | 475,643 | $ 2,129 | $ 3,290 | $152,442 | $ 80,687 | | |
| Totals ........... | $775,840 | $536,143 | $ 2,129 | $ 3,290 | $152,442 | $ 80,687 | $ — | $ 1,149 |

*See notes to financial statements.*

**Statement of Income and Fund Balance**
**General Fund**

| | Year ended December 31 1978 | 1977 |
|---|---|---|
| *Income:* | | |
| Dues earned: | | |
| Regular assessment ....... | $394,790 | $385,178 |
| Less, Commissions paid .. | 586 | 573 |
| | 394,204 | 384,605 |
| Interest and dividends received | 37,411 | 27,674 |
| Rental income ............. | 6,000 | 6,000 |
| Income from collection of A.M.A. dues ........... | 3,070 | 2,125 |
| Gain (loss) on sale of securities ................ | ( 827) | 11,397 |
| Miscellaneous ............ | 1,184 | 716 |
| Gross income ............ | $441,042 | $432,517 |
| *Expenses:* | | |
| Executive Director's office .. | $177,728 | $170,472 |
| Treasurer's office .......... | 4,048 | 3,591 |
| General .................. | 109,713 | 118,414 |
| Building operation ......... | 22,451 | 23,560 |
| Contingent fund ........... | 23,089 | 14,541 |
| Committee allotments ...... | 10,601 | 9,512 |
| Annual and semi-annual meetings ............... | 9,478 | 8,102 |
| Totals .................. | $357,108 | $348,192 |
| Income before loss from Journal operations ..... | $ 83,934 | 84,325 |
| Deduct, Journal expenses in excess of income ........... | 50,027 | 51,292 |
| Net income ............ | 33,907 | 33,033 |
| Fund balance, January 1 ...... | 441,736 | 408,703 |
| Fund balance, December 31 ... | $475,643 | $441,736 |

*See notes to financial statements.*

## Statement of Special Fund Balances
## Year Ended December 31, 1978

### Gurdon W. Russell

| | |
|---|---|
| Balance, January 1 | $ 2,104 |
| Add, Interest received on savings account | 25 |
| Balance, December 31 | $ 2,129 |

### O. C. Smith

| | |
|---|---|
| Balance, January 1 | $ 3,119 |
| Add, Interest received on savings account | 171 |
| Balance, December 31 | $ 3,290 |

### Building

| | |
|---|---|
| Balance, January 1 | $152,442 |
| Balance, December 31 | $152,442 |

### Funded Reserve for Depreciation

| | |
|---|---|
| Balance, January 1 | $ 73,516 |
| Add, Interest on savings accounts | 4,971 |
| Transfer from General Fund | 2,200 |
| Balance, December 31 | $ 80,687 |

### CSMS Ambulatory Care Study Fund (Note 5)

| | |
|---|---|
| Balance, January 1 | $ -0- |
| Balance, December 31 | $ -0- |

### The Connecticut Humanities Council, Inc. Grant Fund

| | |
|---|---|
| Balance, January 1 | $ -0- |
| Balance, December 31 | $ -0- |

*See notes to financial statements.*

## Notes to Financial Statements
## December 31, 1978

### 1. Accounting Policies and Practices

The Society's headquarters premises consisting of land, building and building equipment is recorded in the Building Fund at its original cost.

Depreciation on the building and building equipment is provided for out of current General Fund income by an annual transfer of $2,200 to the Funded Reserve for Depreciation where funds are accumulated to be used for renewals or replacements of the property.

Expenditures for office furniture and equipment, which are not significant, are made, in most instances, from funds of the Gurdon W. Russell funds and are treated as a current year expense of that fund.

### 2. Investments

Investments of the Society at December 31, 1978 consist of the following:

### General Fund

*Common Stock:*

| *Number of Shares* | | *Book Value* | *Market Value* |
|---|---|---|---|
| 667 | American Electric Power Company, Inc. | $ 17,860 | $ 14,090 |
| 150 | Eastman Kodak Co. | 10,035 | 7,594 |
| 350 | Exxon Corporation | 12,577 | 17,194 |
| 150 | International Business Machine Corp. | 38,542 | 44,775 |
| 100 | K Mart Corp. | 3,408 | 2,250 |
| 1,525 | Lucky Stores | 23,649 | 22,494 |
| 200 | Mobil Corp. | 13,321 | 13,875 |
| 500 | Public Service Co. of New Mexico | 10,587 | 9,937 |
| 100 | Schering Plough | 4,023 | 2,963 |
| 300 | Scovill Manufacturing Co. | 6,838 | 5,325 |
| 380 | Tenneco, Inc. | 10,002 | 11,495 |
| 300 | United Technologies Corp. | 12,394 | 11,662 |
| 300 | White Consolidated Industries | 6,650 | 5,063 |
| 300 | Xerox Corporation | 24,331 | 15,975 |
| | Total common stock | $194,217 | $184,692 |

### Gurdon W. Russell Fund

| *Face Value or Number of Shares* | | | |
|---|---|---|---|
| $ 600 | New York, New Haven and Hartford Railroad Co. 4% bonds, due 2007 | $ 398 | $ 480 |
| 900 | New York, New Haven and Hartford Railroad Co. 4½% bonds, due 2022 | 308 | 94 |
| 5 shs. | New York, New Haven and Hartford Railroad Co. 5% conv. pfd. stk.-Series A | 128 | — |
| 1,000 | Boston and Albany Railroad Co., 4¼% improvement bonds, due August 1, 1978 | 820 | 400 |
| | Totals | $ 1,654 | $ 974 |
| | Grand Totals | $195,871 | $185,666 |

### 3. Note Receivable:

The note receivable of $4,999 is a non-interest bearing loan made to the New Haven County Medical Foundation on April 3, 1974. Under the terms of the note, repayment is to be made "when feasible."

### 4. Pension Plan:

The Society has a non-contributory pension plan for its employees and makes actuarially computed annual payments. The plan provides for split-funding whereby part of the payment to the plan is used to purchase individual contracts containing life insurance and part is used to purchase investments.

Payments into the fund were $20,591 in 1978 and $19,089 in 1977.

### 5. CSMS Ambulatory Care Study Fund:

The Society has entered into a contract with the Health Services and Mental Health Administration of the Department of Health, Education and Welfare to conduct a Connecticut Ambulatory Care Study. Work under this contract was to be performed originally over a two-year period commencing October 5, 1972; however, supplemental agreements extended the period to December 31, 1975. Under the terms of the contract, the Society is being reimbursed for the costs incurred in performing services required for the study in accordance with the applicable provisions of the contract. The funds presently obligated by the Government under this contract are $348,994.

At December 31, 1978 expenditures reimbursable under the contract of $348,994 have been incurred, of which $348,884 in reimbursements have been received. However, the Department of Health, Education and Welfare holds the

Society responsible for unaccountable Government property which cost $40.

The report was submitted to the Health Services and Mental Health Administration in 1976 and the final net reimbursement of $60 will be forthcoming upon acceptance of the report.

**6. General:**

The Society anticipated an excess of $1,835 in income over expenses in its budget for the year 1978. Actual operations for the year 1978 resulted in net income of $33,907 or $32,072 more than the amount projected by the budget as shown in the following summary:

| | *Estimated* | *Actual* | *Actual Under or over* Estimated* |
|---|---|---|---|
| Income from dues | $400,000 | $394,204 | $ 5,796 |
| Income from Journal | 65,000 | 69,744 | 4,744* |
| Interest and dividends | 22,000 | 37,411 | 15,411* |
| Building income | 6,000 | 6,000 | — |
| Income from collection of AMA dues | 3,000 | 3,070 | 70* |
| Loss on sale of securities | — | ( 827) | ( 827*) |
| Miscellaneous | 500 | 1,184 | 684* |
| Totals | $496,500 | $510,786 | $ 14,286* |

| | *Budget* | *Actual* | *Actual Under or over* Budget* |
|---|---|---|---|
| Executive Director's office | $176,645 | $177,728 | $ 1,083* |
| Treasurer's office | 4,900 | 4,048 | 852 |
| General | 115,375 | 109,713 | 5,662 |
| Building operation | 23,325 | 22,451 | 874 |
| Contingent fund | 30,000 | 23,089 | 6,911 |
| Committee allotments | 11,235 | 10,601 | 634 |
| Annual and semi-annual meeting | 12,000 | 9,478 | 2,522 |
| Journal | 121,185 | 119,771 | 1,414 |
| Totals | $494,665 | $476,879 | $ 17,786 |
| Excess of actual net income over anticipated net income | | | $ 32,072 |

The Executive Director's office has collected yearly dues for The American Medical Association, of certain county associations and other miscellaneous organizations for the year 1978. At December 31, 1978 all collections to that date had been remitted to the appropriate organizations.

**7. Contingencies:**

The Society's management is unaware of any pending or threatened litigation or unasserted claims and assessments which could have a material adverse effect on the accompanying financial statements.

**8. O.C. Smith Fund:**

The fund was established under the will of Dr. O.C. Smith. The will states that the original bequest of $1,000 be held and invested as a separate fund and the income thereof to be used to pay the dues of any member of the Society who may be unable to pay such dues themselves.

**9. The Connecticut Humanities Council, Inc., Grant Fund:**

The Society was awarded a grant from The Connecticut Humanities Council, Inc. for the project entitled "Humanistic Studies in Medicine: Publication of CHC Project Papers." The grant will run from December 1, 1977 through May 31, 1979 and will not exceed $7,350. At December 31, 1978, the Society received $2,940 of which $1,149 was unexpended. The grant requires matching in-kind contributions in the form of services provided by editors and editorial committee relating to the publication of Humanistic Studies in Medicine.

| | *Years ended December 31* | |
|---|---|---|
| | *1978* | *1977* |
| *Executive Director's Office:* | | |
| Personal services | $148,895 | $145,807 |
| Payments to widow of former executive secretary | 3,000 | 3,000 |
| Staff travel and expense | 4,974 | 3,296 |
| Office supplies | 881 | 524 |
| Maintenance of office equipment | 370 | 301 |
| Printing and postage | 4,504 | 4,381 |
| Telephone and telegraph | 1,326 | 1,171 |
| Sportsmed publication | 1,325 | 1,716 |
| CSMS Newsletters | 1,861 | — |
| Subscriptions | 126 | 42 |
| News clipping service | 376 | 365 |
| Addressograph service | 234 | 160 |
| Xerox rental | 1,470 | 1,419 |
| Social security taxes | 6,764 | 6,500 |
| Unemployment taxes | 1,566 | 1,734 |
| Miscellaneous | 56 | 56 |
| Totals | $177,728 | $170,472 |
| *Treasurer's Office:* | | |
| Printing and postage: | | |
| Collection of society dues | $ 1,221 | $ 1,018 |
| Collection of AMA dues | 555 | 446 |
| Auditors | 1,040 | 885 |
| Computer service | 228 | 311 |
| Investment counsel | 983 | 873 |
| Telephone and telegraph | 21 | 58 |
| Totals | $ 4,048 | $ 3,591 |

| | *1978* | *1977* |
|---|---|---|
| *General:* | | |
| President of Society | $ 1,750 | $ 1,500 |
| Chairman of Council | 1,250 | 1,000 |
| Council expense | 2,647 | 3,444 |
| Delegation to AMA Conventions | 10,485 | 12,744 |
| Legal and legislative counseling | 13,931 | 5,906 |
| Defense of Federal Trade Commission complaint | 44,924 | 61,870 |
| Employees' pension fund | 20,591 | 19,089 |
| Trustee and administrative fees-pension fund | 1,185 | 1,020 |
| Employees' health insurance premiums | 4,310 | 3,841 |
| David A. Grendon Memorial financial aid fund for medical students | 8,000 | 8,000 |
| General insurance | 640 | — |
| Totals | $109,713 | $118,414 |

| | | |
|---|---|---|
| *Building operation:* | | |
| Municipal taxes | $ 6,428 | $ 6,606 |
| Comprehensive insurance | 1,086 | 1,445 |
| Custodial services | 3,248 | 3,479 |
| Supplies | 578 | 499 |
| Electricity, gas and water | 2,158 | 2,511 |
| Fuel | 1,914 | 1,605 |
| Maintenance of grounds | 1,354 | 977 |
| Depreciation | 2,200 | 2,200 |
| Telephone | 2,877 | 2,827 |
| Repairs and replacements | 218 | 1,039 |
| Burglar alarm system maintenance | 390 | 372 |
| Totals | $ 22,451 | $ 23,560 |

| | *Year ended December 31 1978* |
|---|---|
| *Contingent Fund:* | |
| CSMS publications | $ 5,851 |
| Executive Director's moving expense | 4,225 |
| Gift to retired Executive Director | 2,000 |
| K. Brandon - Legislative aide | 1,599 |
| Hospital cost seminars and joint practice committee | 1,209 |
| CSMS Delegates to State Societies, etc. | 899 |
| AMA Regional meeting, Washington, D.C. | 759 |
| CME Meetings-St. Louis and Chicago | 561 |
| CSMS awards | 548 |
| AMA Legislative Conferences - Florida and Colorado | 524 |
| Perinatal Seminar | 500 |
| Seminar - British National Health Service, London, England | 500 |
| AMA Impaired Physicians Council Conference | 499 |
| AMSA Conventions-Georgia and Illinois | 400 |
| AMA Intern-Resident meeting, St. Louis | 360 |
| Contribution to promote change in legislation | 300 |
| Cost risk study | 270 |
| AMA Delegation - Meetings and miscellaneous expense | 260 |
| Publication - "Guiding Principles for Physicians and Pharmacists" | 234 |
| Executive Director's life insurance | 208 |
| Preceptorship Program - Reception for medical students | 208 |
| AMA Leadership Conference | 196 |
| President's expenses | 159 |
| Meetings on 2nd opinion | 128 |
| CACS expense | 115 |
| Ad hoc committees HSA's | 54 |
| Miscellaneous contributions and dues | 535 |
| Miscellaneous | ( 12) |
| Totals | $23,089 |

| | *Years ended December 31* | |
|---|---|---|
| | *1978* | *1977* |
| *Committee Allotments:* | | |
| Public Health | $ 164 | $ 137 |
| Legislation | 3,009 | 3,277 |
| Liaison Committee - Pharmacy Association | 316 | 427 |
| Cancer Coordinating Committee | 283 | 220 |
| Connecticut Advisory Committee - foods and drugs | 125 | 125 |
| Mental Health | 165 | 85 |
| Hospital Committee | 88 | 26 |
| Third Party Payments | 46 | 3 |
| AMA - ERF Campaign | 257 | 223 |
| Perinatal Mortality and Morbidity | 318 | 226 |
| Emergency Medical Services | 181 | 90 |
| Insurance | 57 | 6 |
| Continuing Medical Education | 939 | 621 |
| Cooperation Committee - Medical Schools of Connecticut | 56 | 148 |
| Public Relations | 1,103 | 1,659 |
| Council of New England Medical Societies | 150 | 150 |
| Committee on Program of Scientific Assembly | 123 | 113 |
| Judicial Committee | 181 | 163 |
| Liaison Committee - Social Service Department | 65 | 74 |
| Forum for Medical Affairs | 150 | 150 |
| Professional Liability | 706 | 714 |
| Peer Review Systems | 165 | 213 |
| Statewide Medical Planning | 423 | 126 |
| Drug Abuse Educational Program | 144 | 186 |
| Maternal Mortality and Morbidity | 40 | 32 |
| Continuing Medical Care and Rehabilitation | 7 | 15 |
| Allied Medical Services | 76 | 92 |
| Committee on Medical Aspects of Sports | 182 | 205 |
| Auxiliary to Connecticut State Medical Society | 1,000 | — |
| Miscellaneous Committees | 82 | 6 |
| Totals | $10,601 | $ 9,512 |

| | *Years ended December 31* | |
|---|---|---|
| | *1978* | *1977* |
| **Annual and Semi-Annual Meetings:** | | |
| *Income:* | | |
| Exhibits | $ 6,350 | $ 7,150 |
| *Expenses:* | | |
| Hotel rental | $ 2,500 | $ 2,500 |
| Printing and postage | 2,832 | 3,024 |
| Badges | 194 | 129 |
| Exhibit decorator, rentals and equipment | 615 | 917 |
| Annual Meeting House of Delegates | 3,349 | 3,864 |
| Luncheon and dinner expenses (guest and entertainment) | 2,948 | 2,012 |
| Speakers and visiting delegates | 1,215 | 963 |
| Staff and miscellaneous expense | 202 | 238 |
| Photographs | 85 | 194 |
| Semi-annual meeting | 1,888 | 1,411 |
| Totals | $15,828 | $15,252 |
| Excess of expenses over income | $ 9,478 | $ 8,102 |

### Details of Journal Operations

| | Years ended December 31 1978 | 1977 |
|---|---|---|
| *Income:* | | |
| Advertising (net of commissions) | $ 53,915 | $ 47,754 |
| Subscriptions (non-members) | 3,626 | 3,434 |
| Reprints | 7,976 | 6,574 |
| Authors' alterations | 198 | 237 |
| Authors' subsidies | 3,595 | 3,355 |
| Single copy | 5 | 69 |
| Roster book | 429 | 345 |
| Total income | $ 69,744 | $ 61,768 |
| *Expenses:* | | |
| Personal services | $ 30,243 | $ 26,817 |
| Manufacturing cost: | | |
| Printing-Journal | 66,617 | 64,551 |
| Printing-Roster | 4,530 | 6,400 |
| Postage and handling | 4,879 | 3,672 |
| Reprints | 5,219 | 4,205 |
| Other: | | |
| Printing and postage | 1,822 | 1,187 |
| Office supplies | 549 | 442 |
| Telephone | 660 | 596 |
| Sales tax | 73 | 45 |
| Editorial Board meetings | — | 69 |
| Travel expense | 1,614 | 1,731 |
| Maintenance of office equipment | 302 | 299 |
| Subscriptions | 186 | 241 |
| Registration of copyrights | 250 | 100 |
| Libel and slander insurance | 388 | 550 |
| Social security taxes | 1,823 | 1,541 |
| Unemployment taxes | 537 | 500 |
| Miscellaneous | 79 | 114 |
| Total expenses | $119,771 | $113,060 |
| Expenses in excess of income | $ 50,027 | $ 51,292 |

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## *FALL CANCER UPDATE '79 SYMPOSIA*

A continuing monthly series of half-day seminars for the practicing physician, to discuss new advances in diagnosis, treatment and care in the common cancer sites.

*Sponsored by: American Cancer Society, Conn. Div., Inc.*
*Connecticut Oncology Association*
*Connecticut State Medical Society*
*Yale Comprehensive Cancer Center*

Wednesdays, 1 P.M. to 5 P.M.: Category I CME Credit Approved.

**REGISTRATION FEE: $10 per session, two weeks prior to session. Please mail check and reservation to: Cancer Update, 850 Howard Avenue, New Haven, CT 06519.**

**SEPTEMBER 26, 1979** **MELANOMA AND SARCOMA**

Danbury Hospital

Moderator: Albert Casazza, M.D., Danbury Hospital
Surgical Management of Malignant Melanoma and Sarcoma
Chandra N. Narayanan, M.D., Mt. Sinai Hospital

Chemotherapy of Malignant Melanoma
John Kirkwood, M.D., Yale-New Haven Hospital

Chemotherapy of Sarcomas
Ivan Lowenthal, M.D., Danbury Hospital

Blood Component Therapy in Cancer
Joseph Bove, M.D., Yale-New Haven Hospital

**OCTOBER 10,** **COMPLICATIONS OF CANCER AND ITS THERAPY**

Uncas-on-Thames Hospital
Norwich, Connecticut

**OCTOBER 31,** **BRAIN AND HEPATO-BILIARY TRACT CANCER SUPPORTIVE CARE OF CANCER PATIENTS**

Lawrence and Memorial Hospital
New London, Connecticut

**NOVEMBER 14, 1979** **GYNECOLOGICAL CANCER**

Yale-New Haven Hospital

# Carotid Artery Surgery: To Shunt or Not to Shunt

ALLAN L. TOOLE, M.D. AND HAROLD STERN, M.D.

**ABSTRACT—Over the past seven years the authors have consulted on 150 patients with extracranial vascular disease, From this group there were 68 consecutive operations in 62 patients involving temporary occlusion of the common carotid artery. The operative technique has been developed to be as simple as possible. An internal shunt was used in only three instances.**

**The patients have been separated into two groups. There were 51 operations on 45 patients in the "prophylactic" group. This included transient ischemic attacks 40/36; asymptomatic 5/3, subclavian steal 4/4, a kinked internal carotid in a six-year-old 1/1, post-traumatic internal carotid occlusion 1/1. There were 17 operations on 17 patients with varying degrees of fixed neurologic deficit. There were two procedures for recurrent stenosis. Both patients were in the "prophylactic" group.**

**Eight patients were operated on with "continuous" bruits clinically indicative of poor collateral circulation. Seven of these were done without a shunt and all without complication.**

**Neurologic morbidity was 0% in the "prophylactic" group but was 35% in the fixed deficit group.**

**These results are critically discussed with the aid of a review of the literature.**

It has now been 25 years since the first carotid endarterectomy in this country.[1] Over the ensuing years there have not been uniform advances in our understanding of cerebral disease nor indications for corrective surgery.

It was established early that this operation was not effective in patients with acute fixed neurologic deficit regardless of the degree of internal carotid obstruction.[2] [3] Restoring cerebral flow paradoxically made many patients worse. The experimental work of J.S. Meyer[4] in monkeys presumably explained the concept of the change from the dry ischemic infarct to "wet" caused by increased flow. This concept remains prevalent in surgical thinking.

It has also been relatively well established that endarterectomy in the prophylactic sense, i.e., for patients without fixed deficit (also regardless of degree of obstruction), is effective.[5] [6] [7] [8] Studies to the contrary, however, still raise reasonable doubts, particularly with respect to comparable results of newer modalities of medical treatment.[9]

Despite some evidence to the contrary,[10] [7] [11] the role of endarterectomy in patients with chronic fixed deficits with superimposed mental deterioration or transient ischemic attacks or with "progressive" strokes has not been established.[12] Because of this, certain technical aspects of this surgery are also yet to be established, illustrated by numerous reports of variable cerebral perfusion monitoring methods[13-21] and the wide spectrum of indications for use of an internal shunt.[22-26]

## Report of Cases

This report reviews the recent experience of two surgeons with this operation and records our present opinions based on this experience and a review of the literature.

Over the past seven years the authors have consulted on 150 patients with extracranial vascular disease. From the aforementioned there were 68 consecutive operations on 62 patients which involved temporary occlusion of the common carotid artery. As in most series the common indication for surgery

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HAROLD STERN, M.D., Associate Clinical Professor, Cardiothoracic Surgery, Yale University Medical School.

Reprint requests to: 60 Temple Street New Haven, CT 06510 (Dr. Toole).

Table I

COMPLICATIONS

| | No. of Patients | No. of Operations | Early Neuro | Early Other | Late Neuro | Associated Disease Aortoiliac | Associated Disease Coronary Artery |
|---|---|---|---|---|---|---|---|
| T.I.A. | 36 | 40 | 0 | 3* | 3[A] | 6 | 3 |
| Asymp. | 3 | 5 | 0 | 0 | 1[B] | 3 | 0 |
| Deficit | 17 | 17 | 6 | 0 | 3[C] | 7 | 2 |
| Steal | 4 | 4 | 0 | 1** | 0 | 2 | 0 |
| Kink | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| Trauma | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| | 62 | 68 | 6 | 4 | 7 | 18 | 5 |

A. 1. ? TIA 2 years post surgery. Now 3 years later without symptoms.

2. TIA's 3 years post surgery. Has had temporal artery to MCA bypass on contralateral side. Internal carotid occluded.

3. Recurrent TIA's 3 months post external carotid endarterectomy. Internal carotid occluded.

B. Restenosis requiring reoperation and patch graft.

C. 1. Progressive mental deterioration 3 years post surgery.

2. Two cases of significant late deficit 4 years post temporary postoperative neurologic complication.

* 1 Myocardial infarction, 1 minor wound, 1 bleeding requiring re-exploration.

** 1 Thrombosis of common carotid to subclavian bypass requiring thrombectomy.

was transient ischemic attacks (Table I) (40 operations in 36 patients). Seventeen patients (27.8% of the total) had had previous stroke with some degree of residual deficit. In addition, five operations were performed in three patients without symptoms; four with subclavian steal for a common carotid to subclavian bypass; one (a six-year-old) with a kinked internal carotid; and one with post-traumatic internal carotid thrombosis. There were two procedures for early recurrent internal stenosis.[27] [28]

Early neurologic deficit occurred postoperatively in six (8.8% of the total) (Table II). Three were permanent (4.4%) with two deaths (2.9%) (the only mortality in the series) and three were temporary (4.4%). These all occurred in the group with previous stroke and residual deficit (35% of this group). Mortality and neurologic morbidity was 0% in all other groups.

Other complications occured in five cases (one minor wound infection, one hemorrhage that required re-exploration, one myocardial infarction and one thrombosis of a carotid subclavian bypass requiring thrombectomy).

There has been 100% followup from one month to seven years with a good result in 85.5%. The two re-

Table II

EARLY NEUROLOGIC COMPLICATIONS

| | Year | Age | Neurologic History | Arteriogram | Operative Comment | Onset of Neurologic Complication | Outcome |
|---|---|---|---|---|---|---|---|
| O.W. | 1971 | 62M | Progressive stroke 3 weeks duration | Double Stenosis | Patch | 9 hrs. | Expired. Mural thrombus |
| R.K. | 1971 | 63F | CVA 1 month before + TIA's | Stenosis + ulcer | Good flow | 48 hrs. | No residual |
| A.R. | 1974 | 66M | TIA's | Bi-stenosis | Poor flow | 24 hrs. | Expired. No post mortem |
| S.L. | 1974 | 73M | CVA's 6 months before + Bi-TIA's | Ulcer | | 8 hrs. | 4 years residual |
| R.F. | 1974 | 55F | CVA 1 year before, progressive TIA's 10 days duration | Stenosis + ulcer | Poor flow | Immediately | 4 years residual |
| C.K. | 1978 | 49M | CVA 4 months before + TIA's 12 years | R. occlusion<br>L. stenosis | | 48 hrs. TIA's<br>2 weeks CVA | Residual |

current stenoses were of the intimal type and both occurred within one year of the initial surgery (one in the TIA and one in the asymptomatic group). Both required patch graft at re-exploration. There have been two recurrences of TIA's in the TIA group (one in a patient with external carotid stenosis and complete internal carotid occlusion after only several months and one in a patient who has undergone temporal artery to middle cerebral artery bypass for intracranial disease on the contralateral side three years following endarterectomy). In the group with previous stroke there has been one case of recurrence of mental deterioration after three years of significant postoperative improvement. There were two cases of fixed neurologic deficit four years post surgery (both had temporary neurologic deficit postoperatively).

Because of recent interest in associated cardiac disease this was reviewed. Only five of 61 cases[7] had an obvious problem. There was, however, a striking association with aortoiliac occlusive disease (18 of 61 - 30%). Most of these have had a bypass graft.

There were eight operations on seven patients with a bruit extending into diastole ("continuous")[29, 30] presumably indicative of poor collateral circulation and a low "stump" pressure (Table III). Seven were done without a shunt and all without complication.

The operative technique has been developed to be as simple as possible. The usual time is less than 1½ hours. General anesthesia was used in all cases. Stump pressure measurements have been taken only occasionally. Magnification has been very helpful for a clean endarterectomy and for proper visualization of distal intima. Occlusion time ranges between 12-30 minutes. Ten thousand units of heparin is used early in the procedure and this is reversed with 100 mgm. of protamine after clamp release. Only three of the total series were shunted and these empirically (two because of bilateral occlusive disease (both in the TIA group) and one because of a previous stroke and a bruit extending into diastole). Since 1974 our management has included a surgical delay of six weeks following an acute stroke (on several occasions with the patient remaining on a selective care division in the hospital). Nine cases were done without complication until C.K. (Table III). Despite a four month delay after his stroke, he developed a worsening of his fixed deficit two weeks post internal carotid endarterectomy.

## Comment

The original surgical premise was that carotid endarterectomy restored cerebral blood flow "in patients with functionally significant lesions.[31] Anatomic studies of deficient connections about the circle of Willis suggested the possibility of inadequate collateral circulation. It was a natural sequel, therefore, to develop a technique for internal shunting during surgery. In the authors' opinion, however, shunting complicates and prolongs the procedure. When the concept that embolism caused pre- and postoperative neurologic deficit came into vogue, it was natural that some surgeons would not only question the need of a shunt but raise the possibility of a deleterious effect. Other anatomic studies were used to support a thesis of efficient collateral circulation.[32]

From a review of our experience and supported by a critical review of the literature[23, 25, 33] there does not appear to be an indication for internal shunt in the prophylactic group. Specifically we have not been able to assess an increased risk in this group on the basis of extracranial angiographic evidence or clinical signs of poor collateral flow.[34, 35] We feel mortality and neurologic morbidity should be zero in this group.

There is, however, a formidable risk factor in our hands (and again supported universally by the literature) in those patients with a fixed neurologic deficit regardless of intervening time from injury, angiographic assessment or use of a shunt.[36, 37] We have unfortunately not documented this better with "stump" pressure or other monitoring method. It is difficult to refute circumstantial evidence for embolism as a significant cause of postoperative neurologic deficit[21, 38] particularly in light of the complication of

Table III
"CONTINUOUS" BRUIT

| | | | *Early Complication* | | *Late* | | *Associated Disease* | |
|---|---|---|---|---|---|---|---|---|
| | *No. of Patients* | *No. of Operations* | *Neuro* | *Cardiac* | *Neuro* | *Cardiac* | *Aortoiliac* | *Coronary Artery* |
| T.I.A. | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Asymp. | 2 | 3 | 0 | 0 | 1* | 0 | 2 | 0 |
| Fixed Deficit | 3 | 3 | 0 | 0 | 0 | 1 | 2 | 1 |
| | 7 | 8 | 0 | 0 | 1 | 1 | 4 | 1 |

*Restenosis requiring reoperation and patch graft.

ipsilateral blindness.[39] Our experience, nevertheless, suggests to us that embolism is not always the cause of neurological complication. In contradistinction to others,[25] we consider intraoperative ischemia to be a significant cause of neurologic complication despite the early absence of deficit postoperatively (five of six cases developed deficits from eight hours to 48 hours postoperatively). We feel there is support for this by the natural pathogenesis of cerebral anoxia.[40] The obvious questions are whether an internal shunt would have been beneficial, at least to the extent of lessening deficit degree,[38] or, if not, whether there is at present specific contraindication to surgery in this group (both from short and long term standpoint).[37 5] Unfortunately, our experience does not allow answers to these questions. There is experience, however, that endarterectomy does not change cerebral perfusion.[41] In our opinion, therefore, selective patient vulnerability is as important as collateral circulation and more pertinent than selective use of an internal shunt. Despite this opinion the authors recognize the need for better documentation and plan for the future consideration of cervical plexus block,[9 42 43] an evaluation of barbiturates for cerebral protection[44 45] and "stump" pressure measurements in all patients. Operative shunt, either internal or external,[46] will be considered selectively on the basis of intraoperative findings.

We plan to focus our attention on the fixed deficit group both in our experience and in critical review of the literature.

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# Cancer of the Ear and Temporal Bone

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## Introduction

Malignancies involving the external auditory canal and mastoid constitute a unique group of neoplasms posing one of the most formidable problems in oncologic management. Such cancers, biologically no different from other histologic types found in the head and neck, produce a significant therapeutic dilemma due to the proximity of the brain, major dural sinuses, carotid artery, and cranial nerves. Any or all of these structures may be invaded by cancer and their vital functions can be greatly disturbed by either the disease itself or by subsequent therapy. Whereas the same histologic tumor, arising elsewhere in the head and neck, is aggressively attacked and, as a result, often successfully eradicated, tumor surgery of the temporal bone is often compromised for technical reasons related to anatomic complexity. For this reason, malignancies involving the temporal bone have historically carried a dismal, if not altogether hopeless, outlook. The purpose of this communication is to review current treatment modalities in order to clarify therapeutic attitudes concerning a disease once considered hopeless.

## Incidence

Broders[1] estimates that 84% of aural cancer involves the auricle, 24% the external auditory canal, and less than 2% the middle ear and mastoid. In the following discussion, tumors of the auricle will be excluded, the principal emphasis being placed on malignancies involving the external meatus, canal, and mastoid. The exact incidence of ear cancer is somewhat difficult to ascertain. Reports from the M.D. Anderson Hospital[2] show that only 26 of 48,000 cancer patients registered between 1942 and 1962 suffered from malignancy of the external canal and mastoid, an incidence of 1:2000 new cancer admissions over a 20 year period.

Most patients who develop epithelial cancers of the ear are between 45 and 65 years of age. At the M.D. Anderson Hospital, predominance of male over female patients (7:1) is noted in middle ear cancer, although no sexual predominance is demonstrated for

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carcinoma of the external auditory canal. Although squamous cell carcinoma dominates the histologic types found in the middle ear and external auditory canal, basal cell carcinoma also occurs in the external canal and auditory meatus.

### Anatomy

In order to better understand the vast array of symptoms arising from the disease itself or its subsequent treatment, a brief anatomic review may be helpful. The ear consists of 3 parts, each possessing distinct physiologic characteristics (Figure 1). The *outer ear,* consisting of the auricle and external auditory canal, functions in the collection of sound. The *middle ear*, consisting of the tympanic membrane and ossicular chain, mechanically transforms sound energy of low amplitude, collected over a large surface area (the ear drum), into vibratory energy of large amplitude concentrated over a small area (the oval window). As an embryonic diverticulum of the upper respiratory tract, the middle ear communicates with the nasopharynx via the eustachian tube. The *inner ear* is a sensory organ of sound reception (cochlea) which functions as a complex biologic transducer, converting mechanical energy into electrical impulses to the brain. A portion of the inner ear also provides for the maintenance of equilibrium (semicircular canals, utricle, and saccule). In close proximity to the cochlea, the internal carotid artery passes through the temporal bone superiorly into the brain (Figure 2). Superiorly, inferiorly, and posteriorly, the petrous bone is surrounded by a venous lake, representing major avenues of venous return from the brain. Along the roof of the temporal bone, the superior petrosal sinus drains toward the midline cavernous sinus. Postero-inferiorly, the inferior petrosal sinus empties into the cavernous sinus, whereas postero-laterally, the sigmoid sinus forms the jugular bulb before exiting from the skull through the temporal bone, which forms the floor of the middle cranial fossa and anterior wall of the posterior cranial fossa. The facial nerve (VII), cochleovestibular nerve (VIII), glossopharyngeal nerve (IX), and vagus nerve (X) all penetrate the temporal bone or pass through a portion of it, challenging the physician with the spatial complexity of their anatomy.

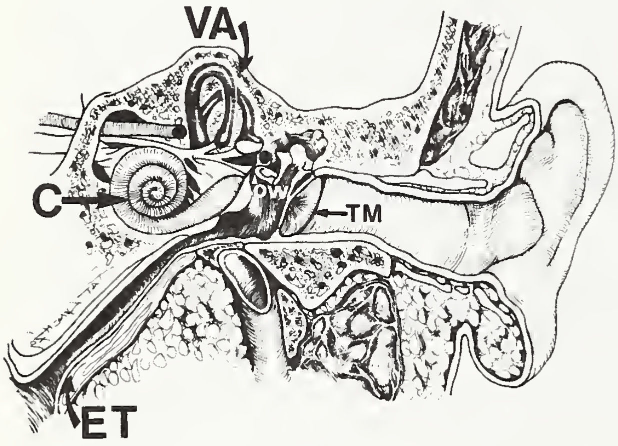

Figure 1
The outer, middle, and inner ear perform functions related to hearing and equilibrium. TM - tympanic membrane. OW - oval window. ET - eustachian tube. C - cochlea. VA - vestibular apparatus.

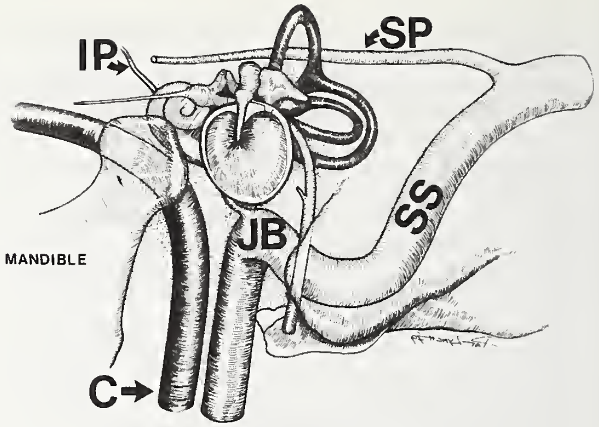

Figure 2
In close proximity to the ear are the carotid artery and major dural sinuses. C - carotid artery. SP - superior petrosal sinus. IP - inferior petrosal sinus. SS - sigmoid sinus. JB - jugular bulb.

### Diagnosis

A large percentage of reported malignancies are preceded by chronic otorrhea. In fact, many patients possess symptoms suggestive of chronic inflammatory disease and seek medical attention only when a change in symptomatology occurs, such as severe pain, bleeding, vertigo, or facial paralysis.

The histologic diagnosis of squamous cell carcinoma is made by biopsy in patients who exhibit changes in symptomatology previously considered to be inflammatory rather than neoplastic. Unremitting pain, bloody discharge, and cranial nerve involvement suggest underlying malignancy rather than chronic infection. Routine X-rays of the skull and petrous bone precede tomographic evaluation. Angiography and computerized tomography assist in delineating the precise extent of disease. The most important role of X-ray evaluation is to determine whether disease has extended into vital areas which would render operative intervention inadvisable. Criteria of inoperability include the invasion of the carotid artery, the temporal lobe dura medial to the entry of the middle meningeal artery, the posterior fossa dura medial to the internal auditory canal, or the body of the atlas or axis.

### Treatment

Surgery and radiation have both been advocated for treatment of cancer involving the temporal bone.

5-year survival rates vary widely from one institution to another. Whereas radiation therapy alone effects a 5 year survival rate of 14% in Sinha's report,[3] surgery alone produces an 18% 5-year survival rate in Conley's series.[4] Radical mastoidectomy prior to radiation therapy is described by Boland and Paterson,[5] who observe that an open mastoid cavity increases the incidence of painful osteoradionecrosis and life-threatening meningitis. A 5-year survival rate of 8% is reported from Memorial Hospital using this method of treatment in 51 patients.[6]

From these early experiences have emerged principles of management which nearly double curability and greatly improve functional preservation. 5-year cure rates for mastoid cancer now approach 30% in a report by Lewis,[7] and 40% in a report by Gacek.[8]

Over the past 3 years, a system of management has been developed at the Yale-New Haven Hospital. Its implementation has resulted in promising therapeutic results for a disease previously considered to be uniformly fatal. Using methods described by Parsons and Lewis,[9] present treatment policy calls for *en bloc* resection of the temporal bone rather than piecemeal radical mastoidectomy. Total gross removal of tumor is followed by postoperative radiation in all cases. By such policy, postoperative radiation is limited to high risk areas determined at the time of surgery, without unnecessary over-exposure to vital areas uninvolved by tumor. Since preoperative radiation produces risk of impaired healing which can result in life-threatening cerebrospinal fluid fistula, postoperative radiation represents an acceptable alternative when total gross removal of tumor is surgically accomplished. Osteoradionecrosis is avoided by meticulous wound closure, using regional skin and muscle for coverage. An open mastoid cavity is assiduously avoided because of the inevitable infection which occurs as the wound heals by secondary intent. It is observed that exposure of bone and superimposed infection are less likely complications of radiation when vascularized flaps are used for closure after *en bloc* resection of the postero-lateral skull base. It should be emphasized that such an attempt is possible only through a team effort, including the participation of the otologic surgeon, neurosurgeon, plastic surgeon, and radiotherapist.

The historical evidence cannot be denied. In the past, principal causes of therapeutic failure and unacceptable morbidity have resulted from: (1) subtotal, piecemeal removal of tumor; (2) irradiation of exposed and infected bone; and (3) intracranial complications caused by impaired healing and sepsis. We recognize such pitfalls, advocating: (1) *en bloc* resection when possible; (2) coverage of exposed bone by vascularized skin-muscle flaps; and (3) postoperative rather than preoperative irradiation.

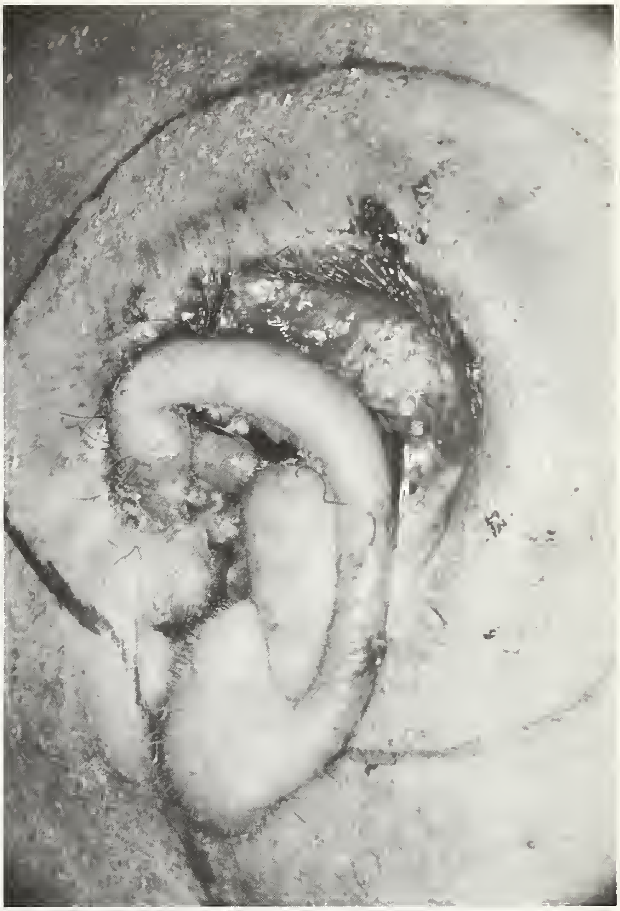

Figure 3
An ulcerating tumor of the external auditory canal has invaded the mastoid bone.

## Operative Procedure

The combined intracranial-extracranial approach for *en bloc* resection represents a massive if not heroic exercise and is, for this reason, worth a brief description (Figure 3). A temporal craniectomy is first accomplished in order to evaluate the medial extent of tumor involvement (Figure 4A). Removal of cerebrospinal fluid from an indwelling lumbar subarachnoid catheter will relax the temporal lobe of the brain for improved exposure when necessary. In general, a tumor is considered unresectable when dura is invaded medial to the foramen spinosum. If dura is necessarily resected medial to this, watertight closure of the subarachnoid space is difficult to achieve using fascial grafting techniques. The probability of subsequent meningitis represents too great a risk under these conditions and the operation may be terminated. On the other hand, if the tumor is considered to be resectable, the craniectomy is extended into the posterior fossa (Figure 4B), allowing the sigmoid sinus and jugular bulb to be mobilized from their attachments to bone.

In order to control the great vessels at the skull

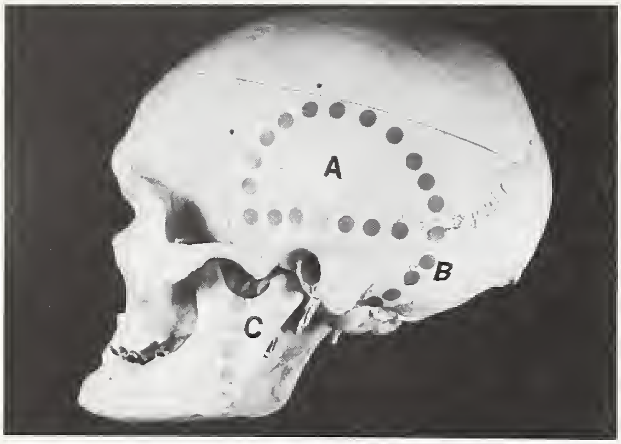

Figure 4

A. Temporal craniectomy is accomplished.

B. A limited craniectomy is extended into the posterior cranial fossa.

C. The mandibular condyle is resected in order to gain exposure of the carotid artery as it courses through the petrous bone.

base, a total parotidectomy with facial nerve dissection is accomplished. The mandibular condyle is resected for exposure of the internal carotid artery and jugular vein (Figure 4C). Through the temporomandibular joint, the intratemporal carotid is identified and, using an air drill, mobilized from its attachment to the temporal bone (Figure 5). This represents the single most important step in allowing the temporal bone to be removed without harm to the intracranial circulation. A partial or subtotal resection of the temporal bone may now be accomplished by creating a controlled fracture across the axis of the petrous bone with an orthopaedic chisel. Depending on the location of the tumor, the temporal bone may be resected lateral to the eardrum (Figure 6A), lateral to the cochlea (Figure 6B), or lateral to the internal auditory meatus (Figure 6C). Any resection medial to the cochlea results in division of the facial and cochleovestibular nerves. When resection is lateral to the cochlea but medial to the eardrum (Figure 7), the eustachian tube is obliterated to prevent potential bacterial contamination from the nasopharynx. The wound is then closed with a skin-muscle flap obtained from either the scalp or the chest (Figure 8).

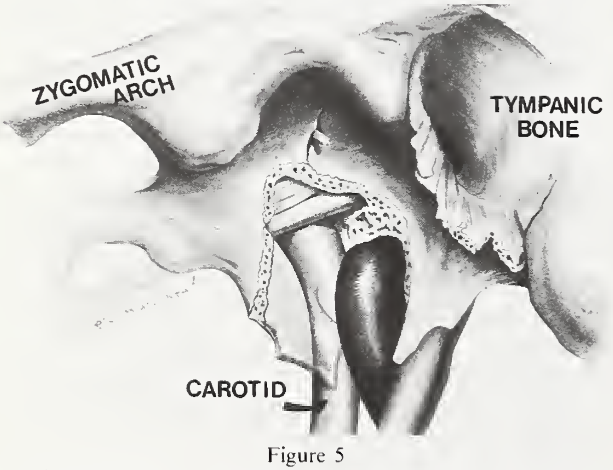

Figure 5
The intratemporal portion of the carotid artery is mobilized from its bony attachments by an approach through the temporomandibular joint.

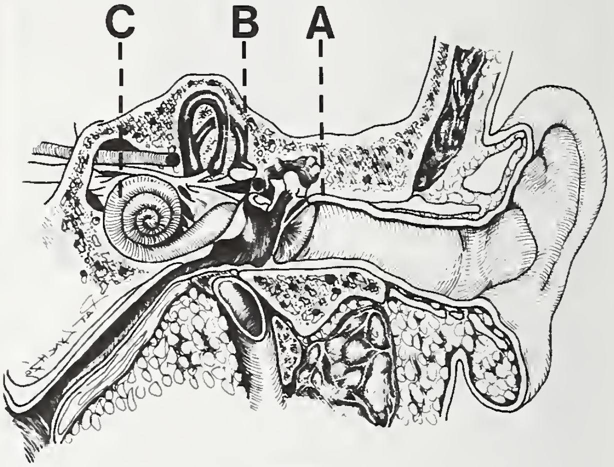

Figure 6

A. A limited partial resection of the temporal bone is indicated when tumor is localized to the meatus.

B. An extended partial resection is necessary when tumor invades the bony external auditory canal.

C. A subtotal resection of the temporal bone is indicated when tumor invades the mastoid or middle ear.

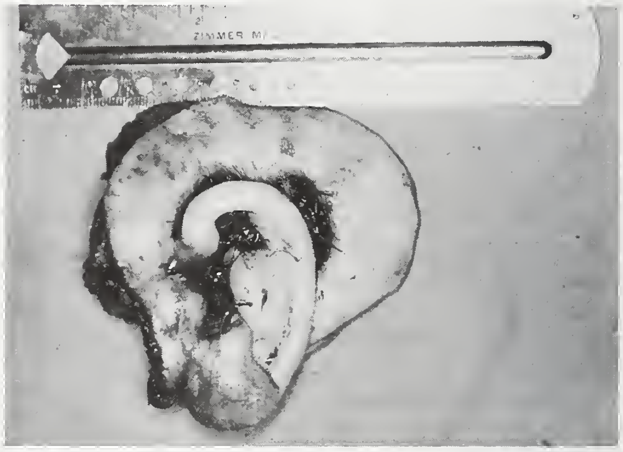

Figure 7
The resected specimen may include the entire auricle and its surrounding skin.

### Results

In 3 years at the Yale-New Haven Hospital (1975-78), 9 patients were evaluated for malignancies of the external auditory canal and mastoid (Table 1). 8 of the 9 patients presented with X-ray evidence of mastoid involvement, whereas one patient had tumor localized to the external auditory canal. In 7 of these 9 patients, biopsies showed squamous cell carcinoma. However, 2 of the 9 patients exhibited basal cell carcinoma recurrent after previous local excision.

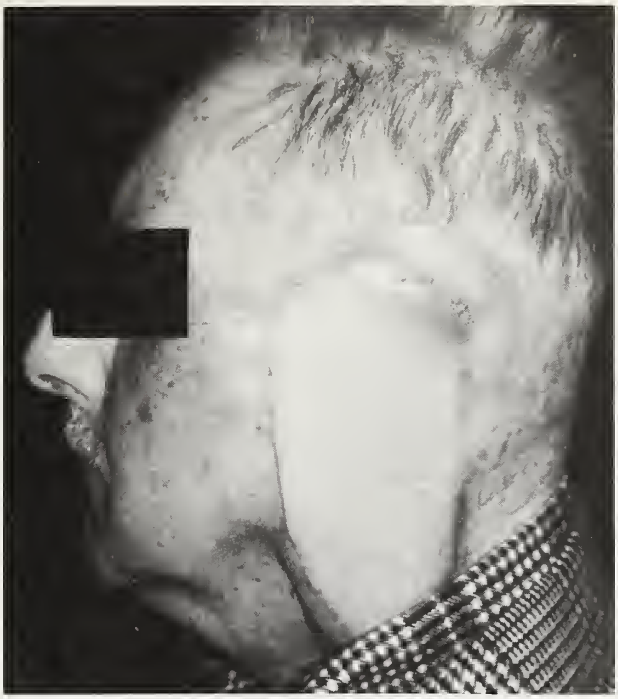

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Figure 8
In this case, closure of the wound is accomplished with a pectoralis major musculocutaneous flap.

Although all patients exhibited resectable tumor, 2 patients refused surgery; both shortly succumbed to intracranial infection resulting from uncontrolled growth of tumor. Of the 7 patients who underwent *en bloc* resection and postoperative radiation, 5 are alive and well without evidence of persistent disease. One patient died one month after successful resection due to temporal lobe cerebritis. Another patient succumbed to tumor which recurred medial to his resection. Although all patients received postoperative radiation, none developed osteoradionecrosis or brainstem injury as a result of this radiation therapy.

## Discussion

Although the number of patients is small and duration of followup too short to formulate statistically significant conclusions, some important impressions are worth re-emphasizing:

(1) Although the degree of surgical complexity is great, morbidity is surprisingly low.

(2) The final decision for resectability is made intra-operatively only after the medial extent of disease is determined by a subtemporal craniectomy.

(3) Total gross removal of tumor can be

Table 1

| *Patient* | *Age* | *Sex* | *Histology* | *Treatment** | *Condition* |
|---|---|---|---|---|---|
| | | | *External Auditory Canal* | | |
| 1. | 63 | M | Basal cell ca | Partial temporal bone resection, temporalis flap | NED** with intact facial nerve |
| | | | *Mastoid* | | |
| 2. | 22 | M | Basal cell ca | Partial temporal bone resection, deltopectoral flap | NED, intact facial nerve |
| 3. | 57 | M | Squamous cell ca | Partial temporal bone resection, scalp flap | NED, intact facial nerve |
| 4. | 77 | M | Squamous cell ca | Partial temporal bone resection, radical neck dissection, pectoralis major flap | NED, intact facial nerve |
| 5. | 77 | M | Squamous cell ca | Subtotal temporal bone resection, radical neck dissection, scalp flap | NED, surgically related facial nerve paralysis |
| 6. | 38 | M | Squamous cell ca | Subtotal temporal bone resection, scalp flap | Died of temporal lobe cerebritis |
| 7. | 80 | M | Squamous cell ca | Partial temporal bone resection, deltopectoral flap | Died of recurrent tumor |
| 8. | 75 | M | Squamous cell ca | Surgery refused | Died of meningitis |
| 9. | 77 | F | Squamous cell ca | Surgery refused | Died of meningitis |

* All surgery was followed by postoperative radiation
** No evidence of disease

accomplished without undue sacrifice of vital intracranial structures, including the carotid artery, sigmoid sinus, and facial nerve.

(4) Radiation therapy delivered postoperatively eradicates residual microscopic tumor in high risk areas determined at the time of surgical exposure. Such practice limits the radiated field, thereby avoiding unnecessary exposure of vital intracranial structures, including the brainstem and spinal cord.

(5) In addition, the use of postoperative radiation does not compromise or impair the healing wound, thereby avoiding life-threatening cerebrospinal fistulization and meningitis.

(6) Osteoradionecrosis is prevented by assiduous avoidance of open mastoid cavities which heal by secondary intent. Open mastoids are contaminated wounds harboring high levels of aerobic and anaerobic micro-organisms. By covering the surgical defect with vascularized skin-muscle flaps, early wound stabilization is achieved without risk of subsequent infection and necrosis.

(7) Elective neck dissections are rarely performed because of the reportedly low incidence of metastases (13%)[10] from the temporal bone.

Cancer involving the petrous bone is not hopeless. The treatment of temporal bone cancer requires the combined expertise of the radiotherapist and surgeon. The cooperation of the otologic surgeon, plastic surgeon, and neurosurgeon uniquely reduces surgical morbidity. Curability, however, is determined by early diagnosis and the completion of high risk surgery and radiation by an experienced team of specialists.

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## Where Organized Medicine Stands on Nursing

In 1970, the AMA's House of Delegates passed a resolution still being cited as the association's position regarding nurses' expanded role:

"The Association is committed to increasing the significance of nursing as a primary component in the delivery of medical services and believes professional nurses are able to assume greater responsibility for medical service under the direction of a physician." The emphasis, whenever the resolution is referred to today, is usually on the last six words. Another resolution passed in 1976 demands the "active participation and approval of the physician" in certifying nurses to perform "tasks within the competence and responsibility of medicine. . . ."

One of the most recent resolutions by a state medical society confirming this view of nursing was passed by the Medical Association of Georgia. In April, its house of delegates passed a resolution stating medical acts performed by nurses should always be done under the "direct supervision of physicians and not as independent agents." In fact, all payments for these "medical services by nurses," the resolution goes on to say, should be made through physicians.

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# Adenocarcinoma from Barrett's Epithelium Simulating Esophageal Varices

ALAN M. NELSON, M.D. AND DAVID I. GRAYER, M.D.

The case of a 35-year-old male with chronic gastroesophageal reflux and radiographic and endoscopic evidence similating varices is described. Adenocarcinoma arising in a columnar lined esophagus was found. The case is reported to stress the malignant potential of the Barrett esophagus and the unusual manner it may present.

A columnar lined lower esophagus has been an associated finding in approximately 10% of patients with clinically apparent chronic gastroesophageal reflux.[1] We are reporting such a case whose presentation radiologically as well as endoscopically simulated esophageal varices.

## Case Report

A 35-year-old white male presented to Bridgeport Hospital in January 1977 for evaluation of an iron deficiency anemia. He gave a four year history of reflux symptoms which had been relieved with antacids. There was no history of weight loss, dysphagia, nausea, vomiting, melena, hematemesis, use of alcohol, aspirin or tobacco. Past medical history revealed that he had suffered a bout of icteric hepatitis in 1965 from which he appeared to have recovered.

Physical exam was not revealing. The stool was negative for occult blood. The hemoglobin was 11.5 gms. Liver function studies were normal. Upper gastrointestinal series showed a hiatal hernia and multiple filling defects in a confluent linear pattern in the esophagus. This was interpreted as esophageal varices (Figure 1). On esophagoscopy, the lesions were described as linear submucosal masses. One of these appeared to have a polypoid tip (Figure 2). No biopsies were taken because of the possibility that these were varices. The patient then insisted upon discharge because of his lack of insurance and it was not until nine months later that he did allow workup.

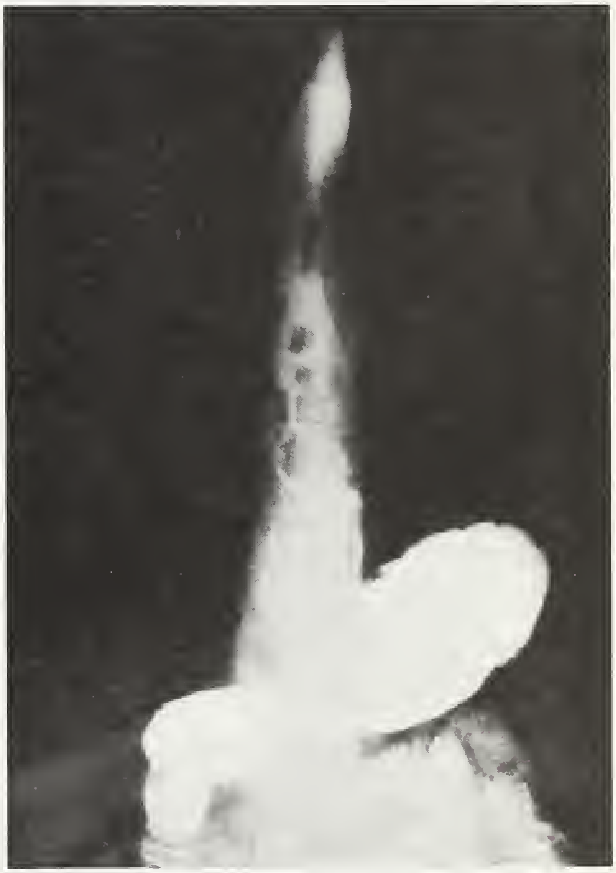

Figure 1
Films from the upper gastrointestinal series showing multiple confluent filling defects interpreted as varices.

At the time of readmission the patient still had reflux symptoms but no dysphagia. Physical exam remained normal. The hemoglobin was 11.5 gms. Portal angiography as well as a superior vena cava and azygous study did not reveal evidence of portal hypertension or "downhill" varices. Barium swallow now revealed multiple irregular polypoid lesions in the esophagus. Endoscopically, the lesions were seen throughout the terminal 15 cm of the esophagus and were separated by areas of normal appearing esophageal mucosa. Biopsy of several of these lesions revealed poorly differentiated adenocarcinoma. The stomach was endoscopically normal. An esophagogastrectomy was performed. Poorly differentiated adenocarcinoma was found transmurally in several

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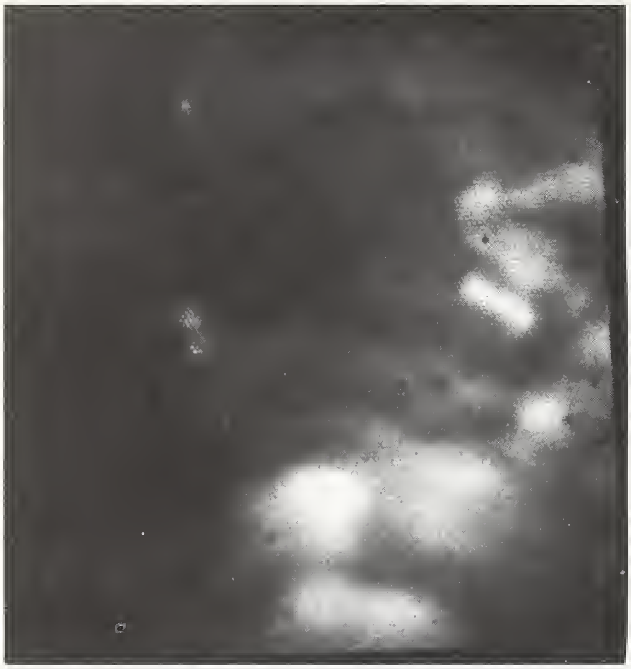

Figure 2
Endoscopic picture of the one submucosal mass with a polypoid tip.

locations throughout the esophagus. Many areas of mucosa were replaced by normal columnar epithelium with areas of carcinoma within. Fourteen of seventeen lymph nodes showed evidence of metastatic involvement.

## Discussion

Esophageal reflux is known to be a cause of esophagitis, stricture and ulceration. Histologically, basal cell hyperplasia as well as extension of the papillae close to the epithelial surface have been shown to have a good correlation with symptoms and reflux studies (pH measurements, supine reflux studies, and Bernstein Tests) in a series of patients where the duration of symptoms is not stated.[2] Other studies have indicated that distal to an esophageal ulcer or stricture secondary to reflux, columnar epithelium may be found.[3 4 5]

When Naef followed 1,225 patients with chronic reflux esophagitis, he found 140 patients with columnar metaplasia of the distal esophagus. Twelve of these patients developed adenocarcinoma of the distal esophagus (8.5%).[1] Of 85 patients followed at the Mayo Clinic with known columnar epithelium in their esophagus, two subsequently developed adenocarcinoma. Five other patients were reported in the same study in whom adenocarcinoma was found to arise from a Barrett's esophagus.[6] There have been additional reports of adenocarcinoma of the esophagus developing in patients with a Barrett's esophagus.[7 8 9 10 11 12]

Our patient is atypical in his age, clinical presentation, endoscopic and radiographic appearance. Reports of patients with adenocarcinoma of the esophagus indicate an average age of 68.6 years.[8] Four patients have been reported below age forty.[6 8 9] Iron deficiency anemia without any symptoms of dysphagia, weight loss or odynophagia is a suprisingly unusual presenting sign. The unexpected benign presentation of adenocarcinoma in a columnar lined esophagus has been noted only several times before.[10 11 13]

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# The Role of Motivation in Patient Recovery

PAUL W. BROWN, M.D.

**ABSTRACT—We are intrigued that some patients get well, while others, with identical lesions, don't. The desire to get well is often as important in the recovery process as the technicalities of our specialties. This motivation is an abstract quality which can't be computerized. It is developed through environment, upbringing, and personality factors; and we know little about recognizing it, developing it, or enhancing it. It may be extinguished by money, litigation, or by bureaucratic excesses.**

**The physician is challenged to discover and to stimulate patient motivation, to get the patient involved in his own recovery. He may use appeals to pride, suggestion, education, and persuasion and may use family members, physical therapists, and others to assist. The goal of the physician is to help the patient to get well, but some patients are motivated not to get well and are supported in this by the intrusion of third parties into the recovery process.**

## Motivation: The Stimulus to Achievement

Patients come to us mainly because of pain, fear, or disability. A few come because they want to look better and some because we can help them to get something. How well we satisfy them depends not only on our technical abilities but also on how well we communicate with them, the amount of confidence we engender, and in how well we understand their problem. As physicians, we know—or should know—that confidence, communication, and compassion are essential to good practice, but we seem reluctant to examine these elements, or to try to measure them or to teach them or to write about them.

Confidence, communication, and compassion have always been important to the patient, but our interest in them now seems inversely proportional to the growth of our technical skills and they are seldom seen in our medical literature. They represent the art, rather than the science, of medicine and, as such, are abstractions.

Motivation, too, is an abstraction. It exists in the mind and spirit and we do not know how to measure it. As a surgeon I take some pride that my technical skills help my patients to get well. Like most surgeons I prefer to dwell on my successes and attribute them to superb judgment and elegant surgery. I tend to explain my failures by bad luck, clumsy assistance, and lack of patient cooperation. A more likely explanation is the level of their determination to get well, their degree of motivation.

Beethoven began to develop deafness while composing his "Moonlight Sonata." His deafness was intolerable and almost led to psychotic breakdown. Nevertheless, he continued to compose magnificent music until he died 26 years later, totally deaf. Such affliction would totally disable most musicians, but Beethoven was not disabled in spirit; he was tremendously motivated to persevere.

Motivation is a stimulus driving a person to achieve a goal, but we really don't know what it is, where it comes from, how to recognize it, or how to develop it in ourselves, our children, or our patients. It is the distinguishing characteristic of the achiever. It may be determined by positive factors such as material or emotional reward or by negative elements such as fear of punishment or failure.

We believe motivation develops in a person as a response to family environment and to parental, ethnic, and religious stimulus, but also is dependent on many factors which we are unable to identify. Why, in a family of several children, does one, no more intelligent than his siblings, develop a greater drive for achievement, or conversely, take a negative course and become a black sheep? The same family environment, the same level of intelligence, the same rewards and punishments: what makes him look for more—or less?

We physicians have long puzzled over why some patients get better and why some don't; why some cope with disability better than others; why one patient's disability is another's determination to

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overcome it. Of the myriad of factors involved, it seems to me that motivation of the patient to succeed figures significantly. A lack of desire by the patient may defeat all our therapeutic efforts, while some patients with seemingly overwhelming impairment persevere in their recovery and again become productive.

Motivation of the patient will seldom have a direct effect on his pathology but it will influence the effect of the pathologic process on the patient, or at least, his response to that process. The highest degree of motivation will not change the course of a malignancy, but it may effect lifestyle and determine how the patient copes with his problem. In obstetrics motivation of the patient has changed obstetrical methods: natural childbirth depends on motivation of the mother, and often of the father as well. The psychiatrist tells us, and tells his patients, that he cannot succeed with them unless they are motivated to get well. The patient who accepts his colostomy with good grace will do better with it than one who does not. The blind patient who is highly motivated to succeed will develop compensatory super touch and hearing: he will not cure his blindness but will succeed in spite of it. This type of compensation is related to motivation, quite the opposite from the compensation allotted by insurance companies and governments.

### Rehab is a Racket

In orthopedics we perhaps have a greater potential for cure or improvement of the patient than in other fields. We have recognized that rehabilitation is a necessary part of treatment, but in our fascination with the technical aspects of surgery, and its rewards, we have allowed another specialty: that of physical medicine—to develop, and to do what we should be doing. With some outstanding exceptions, this specialty has also missed the opportunity and is no longer thriving. The physiatrists and the orthopedists have passed the buck to an attractive auxiliary, the physiotherapists. They, too, are missing the point by emphasizing the patient's passive role rather than stimulating him to become *actively* involved in his own rehabilitation. The physiotherapists have become intoxicated with gadgetry, "modalities" they call them, designed to do something *to* the patient. Rehabilitation is administered to the patient in 20 or 30 minute doses of whirlpool baths, uninspired (and often damaging) passive exercise sessions and boluses of ultrasound or diathermy. They've had the gall to label this "therapy." Palaces called rehabilitation centers have been built for the purposes of prolonging this passive approach to getting well for as long as the public coffers will support it. I much prefer to use the occupational or physical therapist as an educator, a stimulant, or a catalyst, rather than as a doer of things to the patient.

What a waste of time, money, and expectations for a patient with a stiff hand to spend 30 minutes a day, five days a week having his hand passively manipulated! The therapist shouldn't touch that hand. She should demonstrate to the patient how he can use his good hand to help exercise the stiff one. She should impress on him that he must do it not in a 30 minute session with her, but should do it a few thousand times a day at home, sandwiched in between other activities. The trick, of course, is to get him to do it, and here is where the surgeon, the physiatrist, and the physical therapist must understand about the patient's motivation to get well and must know how to develop and exploit that motivation.

These principles are illustrated most graphically in my own specialty of hand surgery. The injured or diseased hand is seldom a simple problem. There are, first of all, the obvious problems of structure, kinetics, sensation, and coordination. These must first be healed, repaired, or substituted for to the best of our technical abilities. The more complex challenge is then to get the patient to use his hand and to work to make it functional. We have learned that results from sophisticated and beautifully executed hand surgery are poor if the patient will not do this. Once repaired, the restoration of function depends mainly on the patient's own efforts and it is our responsibility to help him recognize this.

### The Spectrum of Motivation

Motivation appears to stem from drive, from ambition, and other similar qualities. Pride, perseverance, courage, ambition, and determination are all part of this complex quality. It is a key to successful endeavor and its lack generally means failure. There are a few whose drive for success, whose compulsion for achievement, is so great that they are determined to surmount any obstacle. These Beethovens need only our technical skills. With some explanation from us, they will take care of their own rehabilitation. At the other end of the spectrum is another small group, the losers. They are losers because they have so little motivation that they will do nothing to help themselves. They will not participate in their own recovery; they frustrate and exasperate us and our technical efforts are, in the main, wasted on them.

Our attempts to develop and use motivation will be most fruitful with the majority of our patients who lie between these two extremes of doers and losers. The average patient is motivated to get well and will be sustained in this if given an explanation of his disease, the treatment, and the prognosis. Lack of understanding may foster frustration and may erode motivation. A patient who has had a repair of a peripheral nerve who expects prompt results from surgery will become discouraged and may lose interest in rehabilitating his hand. If, however, he understands the rudiments of nerve regeneration, he can modulate his expectations and his motivation and will continue to work with his hand until surgical results begin to appear months later.

### Motivation As a Tool for Recovery

Informing the patient will stimulate his motivation: education is predicated on communication, but unfortunately, the more specialized and technical we become, the less well we communicate with our patients. The increased frequency of malpractice suits is good evidence of this, admitting as we do, that most suits arise from misunderstanding and failure to communicate. The ill-informed patient with a poor result is frustrated, disappointed, and angry. He is more motivated toward revenge and reward than to return to function. The well-informed patient with a poor result, but with whom we have communicated and tried to stimulate motivation, will not sue. He will be motivated to make the best of what he has and will be more inclined to sympathize with the physician rather than seek vengeance.

Our challenge in this large middle group, of average patients, is to recognize their motivation levels, to develop them, and to use them. We should assume that every patient has some level of motivation and, if not obvious, that it is somewhere latent in his makeup and only awaiting our discovery to be put to use. Even if obscure, it is best to assume a potential for motivation only awaiting our cultivation. We'll be disappointed by some losers but will have some surprising triumphs, too.

There are many tools for the cultivation of latent motivation: apeals to pride, encouragement, approval or disapproval, praise and congratulations, and suggestion may all influence the patient to act on his own behalf. The example of other well-motivated patients may be useful. Sometimes an agreement by an employer to take a patient back to limited work will be a potent stimulus for working harder at rehabilitation. The game plan must be tailored to the individual patient. Either the carrot or the stick may be effective—reward or punishment; gratification or penalty—all are useful, but not so much as education. The better informed the patient is as to what is happening, and why he must do this or that, the more likely he is to mobilize his own resources of pride and persistence.

### Negative Factors

Unfortunately, there are many negative forces at work. We would like to assume that the *patient's goals* and ours are the same, i.e., recovery of function. This is the case with majority, but there are a significant number of patients who are motivated *not* to get well, and their numbers seem to be increasing. There are many reasons why patients may not want to get well—psychic, social, economic, marital, and other reasons, obscure and unrecognized by even the patient himself. The patient who sees a crippled hand as a means of getting sympathy or wanted attention will resist its recovery; the recognition may be more important to him than pride, money, or respect. Another may use his injury as a means to escape from an intolerable job or family situation. I well remember an intelligent woman whose metacarpals had been malaligned in a family brawl. She refused to have the deformity reduced, preferring to keep a grotesque hand to constantly remind her husband of his guilt. She interpreted her disability as an instrument of power and this gratified her more than a functional hand.

Where compensation is sought or litigation is pending the patient may be negatively motivated for recovery. He is positively motivated toward other rewards. The poorly motivated patient given a monetary reward for disability is not inspired to overcome his disability. A system promising cash rewards for a sustained disability predictably will sustain disability rather than stimulate rehabilitation. This will be particularly true for the marginal achiever. Our attempts to rehabilitate him and our appeals to his pride will fail as such a patient has different goals than ours.

Litigation compounds this problem. The attorney for the plaintiff in a personal injury suit not only has different goals for the physician, he has exactly the opposite goals. He wishes his client to appear as disabled as possible—the more obvious the disability, the higher the award. He, too, uses motivation as a tool, but with different aims. He can seduce the weak patient with promises of money, whereas the physician has only hard work and a hope for better function to offer.

The politician is much worse than the attorney. The latter may defeat our best efforts with the occasional individual but the politician, with his beguiling offers, tends to deprive thousands of marginal achievers of motivation. The practice of medicine in a socialist system, despite its benefits, has become quite depressing in this respect. In Scandinavia, Great Britain, and Australia, to name only a few countries, the physician is often completely frustrated in his attempts to motivate the patient to rehabiliate himself and to return to work. In these countries, the social system often pays a laborer as much to be disabled as he can earn on the job—a subversion and perversion of motivation. Contrast that with a society in which actual survival is marginal, where it is either work or starve. In such an environment, the motivation is strong indeed to return to function!

I'm not advocating a return to the dubious advantages of marginal survival, but I am suggesting that physicians must understand the principles of patient motivation and find ways to utilize them for patient recovery and to counter negative motivational pressures.

# Psychiatry in Organized Medicine

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Medicine today, challenged by the prospect of a national health care system, pressure from regulatory agencies, the problem of escalating costs, the malpractice crisis, and the rush of new technology, must organize more effectively to make its voice heard in national councils. It is now imperative that all the components of organized medicine work closely together. Psychiatry is no exception.

Most specialty societies are closely integrated with the state and county medical societies as well as with the AMA but in psychiatry there has been a clear lack of integration. The AMA and APA as well as the state and local medical and psychiatric societies must move towards each other rather than continue to be essentially parallel organizations. This requires a change in thinking for many psychiatrists as well as for other physicians with whom they work. Furthermore, the large number of psychiatric patients, as well as the percentage of hospital beds necessary for their care, makes it essential that psychiatrists be actively involved in future plans for the delivery of health care.

Many physicians do not know that, in contrast to most other specialty organizations, the American Psychiatric Association is a national organization with 20,000 members and a highly organized and effective central office in Washington with considerable legislative and political experience. Under its auspices the district branches of the society are active on the state and local levels. The Connecticut State Psychiatric Society has 23 active committees including those on confidentiality, continuing medical education, psychiatry and the law, ethics, insurance, peer review, and legislation. The legislative committee follows all relevant legislation very closely and sponsors new legislation.

Several areas of significance in psychiatry today have implications for all branches of medicine. We will focus on internal issues that need to be solved, as well as psychiatry's relationship with the outside world. We would hope that, with a recognition of the commonalities involved, a closer working relationship would naturally ensue between the state medical and psychiatric societies, that psychiatrists would wish to be involved to a greater degree in medical society committee work and that they would be sought out more by the state and local medical societies for such work.

### Psychiatrists and Other Mental Health Professionals

Most psychiatrists now appear to be recognizing that they are physicians who specialize in psychological medicine. Psychiatry has tended to overextend itself into areas where it does not have real expertise, partly because every field has to experimentally find its limits of usefulness, partly because of the wish that it could be useful, and frequently at the pressured behest of others who would wish that it could be useful. Psychiatrists are trained to treat people who are definably ill. Social and cultural factors may be complicating or contributory towards illness but such factors are not the responsibility of psychiatrists to change when they are in their professional role.

One colleague notes, for example, that the person who is despondent because he cannot obtain employment is reacting realistically to a realistic situation when unemployment is high. He views this person as no more suitable for psychiatric treatment than is the person who is appropriately mourning the death of a loved one. He would argue that the point at which such a person should be treated is where that stress creates a definable illness manifested by clearcut symptomatology. It is at such a point that psychotherapy can be of help.

Psychiatrists and other mental health professionals have different backgrounds and training, different areas of expertise, and some overlapping areas of

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expertise. It is important that they work together with mutual respect. Because he is a physician, the psychiatrist is in the best position to do the initial evaluation of the emotionally ill person. He has the broadest training.

Psychiatrists have argued about who they are, how they differ from other mental health professionals, and what distinguishes psychiatric treatment from new approaches in counseling that are directed towards personal growth. In the Sixties, some psychiatrists moved away from the medical model and flirted with the social scientists and behaviorists for a time. More recently there has been a movement back to the medical model with ideas from other fields seen as useful, enriching, and complimentary. Most psychiatrists, not only those in general hospitals or those interested in psychosomatic medicine, have considered themselves physicians first. It is impossible to divorce psychological mechanisms from a total biological entity. Medical school training brings to psychiatry an important background and understanding of the complexity of interlocking systems within each human being. Furthermore, it inculcates an approach to the care of the whole person and an emphasis on treatment responsibility unique to the medical profession. In 1970, the American Board of Psychiatry and Neurology eliminated the internship as a requirement for certification in psychiatry. The influence of medical training on the psychiatrists was consequently diluted. Because of the deleterious effects of the elimination of the internship, it has now been restored.

The Department of Psychiatry at Albert Einstein College of Medicine in New York[1] studied internship and non-internship residents in their first year through chart reviews and staff ratings of performance and concluded that those without internships were disadvantaged on the inpatient service. A follow-up study indicated that little change tood place in second or third years of residency. Non-internship residents tended to use medical consultation less, medication less, and the laboratory less. Perhaps the most important finding was that considerably more patients of non-internship residents terminated treatment prematurely and unilaterally. This would clearly seem to indicate that the quality of management of patients by non-internship residents was inferior to that of internship residents. The supervisory ratings of the two groups did not differentiate in the categories of appearance, personality, reliability, diligence, and resourcefulness. These traits may be independent of specific previous training. The percentage of outstanding and excellent ratings was significantly higher for intern residents on such items as clinical judgment, history-taking, and attitude towards patients and attending staff. While the specific experience of internship is not the only determining factor for the acquisition of these assets, it certainly seems to be an important one.

The internship year provides the challenge of making independent decisions, dealing with emergencies, death, inter-professional relationships, and any number of issues which would tend to spur growth and maturity. The intern becomes a physician. It is not just that he increases in knowledge of illness and in self-reliance; he also acquires a basic philosophical and traditional stance that enables him to take responsibility for another life.

What may be missing in the thinking of the non-internship resident (as well as frequently in other mental health professionals) is well expressed by Doctors McIntyre and Romano.[2] They emphasize the usefulness of the medical model in the evaluation and treatment of the psychiatric patient. They state that most clinicians would accept the statement that all elements of human functioning, including thoughts, emotions, and behavior, in health as well as in disease, are the products of a complex set of interactions involving multiple levels of organization. A wide variety of physical conditions can precede or follow, exacerbate or be exacerbated by, resemble, interact, and co-exist with the spectrum of psychiatric states. They note, following a survey, that a third of psychiatrists do physical examinations and the vast majority of the other two-thirds omitted the physical examination either because another physician had done it or because they had referred their patients to another physician to do it. Clearly, any dichotomy of physical and psychiatric conditions is untenable.

One of the more important differences between the psychiatrist and other mental health professionals is that while the same observations may be made about human behavior, those observations are often understood differently in the light of his medical knowledge and his generally more rigorous training.

### Insurance Coverage for Mental Illness

The definition of what constitutes treatment for mental illness, as contrasted with other psychological approaches that expand the personality, assist personal growth or help with normal life experiences, is crucial to the determination of coverage for psychiatric treatment under a national health insurance plan. The legislators and planners fear the open-ended and somewhat intangible transactions in the psychotherapeutic process which are difficult to monitor and control. Research evidence for the effecitveness of psychotherapy has been steadily accumulating over the last 15 years and now amounts to over 100 controlled outcome studies, most of which have yielded positive results. The question of cost is of major importance to any consideration of insurance coverage for long-term intensive psychotherapy. The evidence is that psychotherapy can be provided at a reasonable cost in a comprehensive health care plan.

Experience with the Blue Cross-Blue Shield plan operating under the federal employees' health benefit program has shown that the availability of unlimited intensive psychotherapy with co-payment coverage does not seem to cause any appreciable increase in the number of people utilizing this form of treatment. Total costs in 1973 and in 1974 leveled off in the area of 7.4%. Various studies of private practice have indicated that the availability of insurance coverage does not significantly affect the degree of utilization of psychiatric services.

Studies in this country and West Germany, which has a national health insurance system with coverage for long-term intensive psychotherapy, including psychoanalysis, have shown that psychotherapy not only helps patients with their emotional problems, but also reduces their tendency to seek unnecessary medical treatment, diagnostic tests, and hospitalization. A very strong case can be made for the cost effectiveness and economic feasibility of insurance coverage for long-term intensive psychotherapy.

At the present time, psychiatric patients are short-changed in many of the existing health care plans, including Medicare, Medicaid and Blue Cross-Blue Shield (CMS). The level of Medicare reimbursement has been fixed at 50% of the customary fee by virtue of a special discriminatory provision in the law which applies only to the psychiatric patient. Welfare reimbursement for psychiatric treatment is usually below the level for other medical specialties. CMS, which accounts for a large proportion of reimbursement of hospital treatment, pays even less than welfare for a hospital visit (after a $200 limit has been exceeded); in the case of the emergency room psychiatric consultation, CMS pays less than 50% of the welfare rate. Such restrictions affect the availability of and access to psychiatric services for the public. Closer liaison and better communication between the psychiatric and medical societies would result in more effective representation of the psychiatric point of view.

### Psychiatry and Government

Oddly enough, the gathering criticism of psychiatry of the last ten years comes at a time when there has been spectacular progress. In the last 20 years, the number of patients in state mental institutions has decreased from 600,000 in 1956 to less than 200,000 now. There have been advances in psychopharmacology and psychophysiology that have dramatically improved the treatment of depressive illnesses, manic-depressive psychosis, and schizophrenia. Psychotherapeutic techniques have also improved. People tend to forget how difficult it was to manage the anguish of a severe psychosis prior to the advent of phenothiazine medications. At this point, they only focus on side effects and their fear of the abuse of chemical restraint. It must be possible to guard against abuses of personal liberty and retain the rights of patients to make informed choices, without ignoring the needs of those patients who are incompetent to make such choices. They must not be deprived of essential psychiatric treatment.

Legislative encroachments on the independence of the physician in selecting appropriate treatment for his patient not only affects psychiatry but all physicians. In our field most of this legislation has been sponsored by patient advocate groups representing a civil rights movement for patients. Civil rights legislation for the emotionally ill is generally advantageous to good patient care in that it promotes a sense of autonomy and personal responsibility for decision making which is consonant with the aims of treatment. There tends, however, to be extremist views on the part of some civil rights advocates who believe that physicians have too much power and are too paternalistic. The recognition that some emotionally ill people temporarily lack the capacity to exercise their civil rights when their reasoning and judgment is profoundly affected by their illness gets lost.

In Massachusetts, for example, there is an absolute limit on the number of electroshock treatments which can be given to a person in a lifetime. In Connecticut, the law states, "If it is determined by the head of the hospital and two qualified physicians that the patient has become incapable of giving informed consent, shock therapy may be administered on order of the Court of Probate if, after hearing, such court finds that the patient is incapable of informed consent *and there is no other reasonable alternative procedure*." That the patient has due process is perfectly acceptable but the implication of the final phrase is that the Probate Court judges should "save" the patient from electroshock treatment if possible. One can argue the merits of electroshock as a form of treatment. One can question whether it has been abused on occasion. However, the paramount issue here is the undercutting of the physician's right to make decisions about what is or is not proper treatment.

Another example is a case in Massachusetts where a judge issued an injunction against a psychiatric hospital requiring it to stop giving medications to patients against their will, whether or not they were competent to refuse treatment. There followed a rash of assaults, fire setting, and self-destructive behavior on the wards.

A useful example of cooperation between the medical and psychiatric societies occurred in a recent legislative session when the advocates of orthomolecular therapy attempted to pass legislation that would mandate this treatment in the state hospitals and also require the Department of Mental Health to conduct research programs into this particular form of treatment. A substantial amount of evidence has accumulated to invalidate the theory that orthomolecular therapy cures schizophrenia.[3] The psychiatric society was joined by representatives from the county medical societies, who spoke convincingly about the possible risks and side effects of such treatment and the legislation did not pass. This was also a good example of effective political action motivated entirely by concern for the patient's interests. While professional self-interest and concern for patients is not necessarily mutually exclusive (in fact, they often coincide), in this case there was no self-interest.

### Psychiatry and Bureaucratic Control

The State of Connecticut Mental Health Planning is at the mercy of an astonishing number of diverse committees and planning groups. Each has some official and bureaucratic status. Each has its own separate plan for the future of psychiatric treatment in the state. The people involved in the process are well-intentioned and some are experienced, but the duplication, rather multiplication, of the planning process has a potential for chaos. The organizations involved include the Catchment Area Councils, the Regional Mental Health Boards, HSA's, SHCC, SHPDA, the Advisory Council on Mental Health, the Department of Mental Health, and Department of Health, and probably a few others that the authors have not heard about. All of these organizations have some share in the planning process; many of them have compiled needs' assessment and drawn up plans, while their goals and objectives are not always the same. Some of the organizations communicate well with each other; a few are not speaking to each other at last report. The situation is more or less the same in the other states. While the authors are not against the principle of a national health plan, they are concerned with what may be around the corner under such a plan in terms of bureaucratic inefficiency and control, and its effects on patient care. One has only to look at the example of the National Health Service in Britain and the fate of elderly patients in need of dialysis to see what might happen, particularly when rising costs become a problem.

### Conclusion

The authors have attempted to delineate some of the issues of current concern to organized psychiatry in respect to its relationship with other mental health professionals, the financing of mental health care, and governmental and bureaucratic problems. It is their contention that organized psychiatry has had experience in all of these areas and others and can fruitfully contribute with other physicians in the state and local medical societies. At the same time, the medical societies' understanding and advocacy of psychiatry's needs would also prove helpful.

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# The Clinical Center:
# Twenty-five Years of Research for People

## Introduction

When the National Institute of Health opened its first laboratory at the Navy Annex in 1930, its role was to conduct the Federal Government's biomedical research programs. Its focus was primarily on infectious diseases.

Today's ten Institutes* share office and laboratory space in 42 buildings on the 306-acre Bethesda campus headquarters and in other buildings scattered throughout suburban Maryland. The National Institute of Environmental Health Sciences is located in Research Triangle Park, North Carolina. The role of the Institutes has remained the same; however, their focus now encompasses all diseases affecting mankind.

Sixty-six percent of Federal biomedical research and 40% of all biomedical research in the United States is supported by the National Institutes of Health. Approximately three-fourths of NIH funds go to support research conducted at centers around the Nation. The remaining one-quarter are reserved for research at the Bethesda facility.

Only one building on this reservation—the Clinical Center—is devoted entirely to clinical research.

A visiting foreign scientist working at the Clinical Center in this, its 25th year, was overheard to say, "What is hard to comprehend is that the amount of research done in this building in one week is equal to all the medical research done in my country in one year."

With over 3,700 employees devoted to biomedical exploration and clinical excellence, the volume of work done at the Clinical Center indeed makes it unique. But what makes it most special, perhaps, is the setting in which that work is done. There are 541 hospital beds, with twice as much space devoted to laboratories as to patient care areas. This means that biochemists peering down microscopes at proteins isolated from diseased lungs can hear patients with emphysema coughing across the hallway. And neurophysiologists studying nerve axons in squids glance occasionally at television monitors taping epileptic seizures in infants. Pediatricians sit down to coffee in the cafeteria with molecular biologists and biostatisticians as children skim by in wheelchairs.

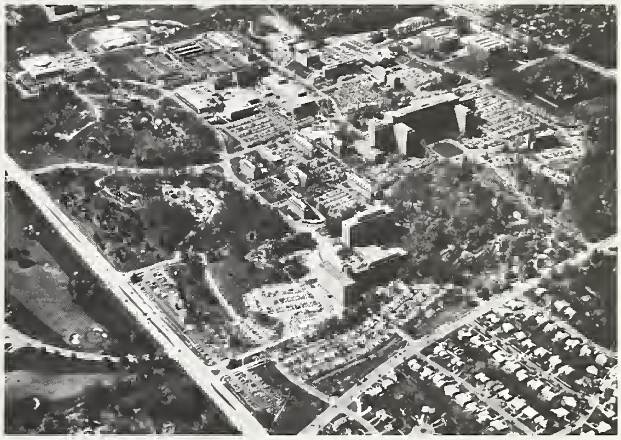

Photo 1
The Clinical Center, in the right upper quadrant of this aerial view, dominates the 306-acre National Institutes of Health "campus."

Physically the Clinical Center is a 14-story red brick building, with twelve stories each accommodating approximately twenty-five patients and one hundred laboratories. The Center was specially designed to bring patient care facilities close to research laboratories so that the new findings of basic and clinical scientists can be moved quickly from the labs to the treatment of patients.

Nearly one thousand physicians from the eleven NIH institutes conducting research at the Center provide the medical care. Nursing care and other support services are provided by Clinical Center staff.

Patients, upon referral by their physicians, are admitted to clinical studies conducted by the Institutes. Each patient is admitted because his case has already been diagnosed as having the particular kind or stage of a disease or other condition that is required for an Institute research project. For this reason, patients can be admitted only when recommended by their own physician, who also supplies the

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*National Cancer Institute; National Heart, Lung, and Blood Institute; National Institute on Aging; National Institute of Allergy and Infectious Diseases; National Institute of Arthritis, Metabolism, and Digestive Diseases; National Institute of Child Health and Human Development; National Institute of Dental Research; National Eye Institute; National Institute of General Medical Sciences; and National Institute of Neurological and Communicative Diseases and Stroke.

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Prepared by Thomas H. Flavin, NIH News Branch, and the staff of the Clinical Center Information Office, NIH, Bethesda, Maryland 20205.

Clinical Center with the medical information needed for selection of suitable cases. The number of beds available for a particular study and the length of the waiting list of qualified patients also are important in determining whether and when an individual can be admitted. Research on a particular disease may be such that only one or two patients can be studied at a given time.

Most of the clinical research is concerned with the more common serious diseases. For this reason the Center seldom admits patients with rare and unusual diseases or those with conditions that doctors have been unable to diagnose. The Clinical Center is not a diagnostic clinic and its research facilities are not used for this purpose.

### Conquering Hepatitis

Significant advances have been made in the control of post-transfusion hepatitis since the Clinical Center opened its doors in 1953. A large number of these advances are due to the Center's Blood Bank.

As early as 1957 the Blood Bank had published its first research paper delineating the post-transfusion hepatitis problem, firing the first salvo in what was to be a long but largely successful campaign.

In 1964 an antigen—the Australia antigen—was discovered, first in a blood sample collected from an aborigine and then in the blood of leukemia patients by Blood Bank Immunology Chief Dr. Harvey Alter and National Cancer Institute investigator Dr. Barruch Blumberg. Later Dr. Blumberg, who was then working in Philadelphia, linked the antigen with hepatitis. For this discovery he was awarded the Nobel Prize.

Paralleling this laboratory work was a clinical study conducted by the Blood Bank that was published in 1970. Patients undergoing open-heart surgery at the Clinical Center were divided into two groups, one that received commercial blood, the other group that received blood from volunteers who had donated at the Clinical Center or the Washington Red Cross Center. Within six months after the operation, over 50% of those receiving commercial blood developed hepatitis. No hepatitis developed in those receiving voluntary blood. With this concrete evidence in hand, the Clinical Center implemented a supply program that relied exclusively on voluntary blood provided by NIH employee donors and the Red Cross.

Subsequently, Blood Bank Chief Dr. Paul Holland, working with other researchers in the Blood Bank, the National Institute of Allergy and Infectious Diseases, and the National Heart, Lung, and Blood Institute, demonstrated in another clinical study that transfused blood containing the antigen often results in patients getting hepatitis. These studies laid the foundation for the current Food and Drug Administration ruling that every blood unit be tested for the antigen—now called hepatitis B surface antigen (HBsAg)—before transfusion.

With the sole use of volunteer donors and hepatitis screening with a radioactive test for the hepatitis B antigen, it was hoped that blood from the Blood Bank would soon be hepatitis free. This was not the case. Instead, 8% of transfused patients continued to develop hepatitis after transfusions. This frustrating experience prompted the most recent and perhaps most important discovery made at the Blood Bank—the identification of a new form of viral hepatitis, called non-A, non-B hepatitis. Dr. Alter and his colleagues have developed an animal model for this newly recognized disease. Blood Bank researchers are currently attempting to develop a test to identify carriers of non-A, non-B hepatitis who may inadvertently transmit this disease to patients through their blood donations.

Photo 2

Through a porthole in the observation deck of one of the operating theaters, a photographer records the techniques used in open heart surgery.

### Surgery in the Round

No overview of Clinical Center highlights would be complete without touching on the surgical successes and advances achieved there.

Dr. Andrew G. Morrow, who has been Chief of Cardiac Surgery since the Clinical Center opened its doors, began his early work in open heart surgery that culminated in 1960 with the very first successful removal and replacement of the mitral valve in the human heart.

The valve used by Dr. Morrow was developed by him and Dr. Nina S. Braunwald. It was made of flexible plastic and was designed to mimic the natural mitral valve. The valve was difficult to place within the heart, however, and was supplanted in that same year by the ball valve developed by Dr. Albert Starr and engineer M.L. Edwards at the University of Oregon. The Starr valve was rugged and dependable but a major drawback was the origin of blood clots from the bare metal arms of the cage which enclosed a silicone rubber ball. Such clots occurred despite treatment of the patient with anticoagulants.

Investigations at the Clinical Center's Surgery Branch and elsewhere found that the clotting problem could be alleviated by covering the cage arms with a teflon-type fabric. This improved design, the cloth-covered Starr-Edwards valve, was first implanted in a patient by Dr. Morrow, in the new Surgical Wing of the Clinical Center in February 1967. By December of 1968, more than one hundred patients had received the improved valve at the Clinical Center. Follow-up studies have since confirmed that the fabric covering indeed markedly reduces the clotting problems.

During the same period further research was being done on other suitable materials and sources for artificial valves. A promising development was a pig heart valve preserved and sterilized by glutaraldehyde and mounted on a flexible polypropylene frame or "stent." This design is known as the Hancock porcine xenograft, named after W.D. Hancock who perfected this valve configuration with Dr. Robert Reis and Dr. Morrow at the NIH.

The Hancock xenograft was first used to replace a mitral valve in a patient at the Clinical Center in July of 1970. The porcine valve has proven itself to cause far fewer clotting problems, so much so that anticoagulant drugs are not usually prescribed for its recipients as they usually are for other valve replacement patients. The Hancock valve also seems not to cause hemolysis, the destruction of red blood cells by the rougher surfaces of other artificial valves which necessitates iron supplementation. Its size makes it especially suitable for mitral valve replacement where space limitations are an important factor. Its only drawback may be in durability, but this seems less likely as more and more early recipients cross the critical five-year period without valve failure.

Another area of contribution by the National Heart, Lung, and Blood Institute's Surgery Branch has been in the design of artificial pacemakers. It was Dr. Andrew Morrow who first conceived of using a nuclear power source, plutonium 238, to extend a pacemaker's useful life from 11 to 20 years. Such a pacemaker power cell was subsequently developed under contract by the Atomic Energy Commission. The capsule which contained the radioactive plutonium withstood a whole battery of tests such as point blank impact from a .44 magnum handgun and a simulated cremation at 1,000 C.

After extensive testing in dogs, the first of these pacemakers was implanted by Dr. Charles McIntosh in a patient in the Clinical Center in April of 1973. The patient had received her first conventional pacemaker in 1962 and had undergone 10 pacemaker-related operations in the following decade. Since that time, the nuclear-powered pacemakers have shown themselves to be particularly suitable for younger patients who have a longer life expectancy and thus can derive full benefit from the lengthy service and reduced operating costs.

### From Life Island to the Space Suit

The Clinical Center has been the site of some of the most effective treatments developed for specific forms of cancer. The first successful cure of a solid tumor with anticancer drugs was achieved in 1955 by Drs. Roy Hertz and M.C. Li. Drs. Mortimer B. Lipsett and Griff T. Ross, who are now Director and Deputy Director of the Clinical Center, extended these studies. They reported that choriocarcinoma, a rare cancer of the placenta that can occur following pregnancy, is almost entirely curable by chemotherapy if it is detected soon after it has developed.

Similar chemotherapeutic successes have subsequently been reported by other National Cancer Institute investigators working at the Clinical Center, particularly in acute childhood leukemia and in Hodgkin's disease.

A common problem shared by many forms of

Photo 3
The isolator itself must be thoroughly cleaned and sterilized by the Clinical Center nurses. The patient, too, must be made as germ-free as possible. Starting two or three days before entering, she is given numerous baths and showers. After each bathing, a complete change of bed clothes and linen is made. Even the patient's internal system is specially prepared for germ-free living. All items must be sterilized before being placed in the isolator. Sterile emergency equipment must be on hand in the "Life Island" room, which must also be kept germ-free. All the patient's food and beverages are specially prepared and sterilized.

cancer chemotherapy and some other treatment regimens is that these treatments interfere with the body's immune system, rendering the patient defenseless against infection. Leukemia patients are in double jeopardy because the disease itself interferes with the immune system. Despite the use of antibiotics, infection is ultimately responsible for about 70% of all deaths in acute leukemia.

In the 1960's the NCI, using methods first developed for breeding germ-free laboratory animals, began experimenting with different forms of patient isolation in order to prevent infection. The first system put into use at the Clinical Center in 1965 was a soft, clear plastic canopy that enclosed the hospital bed. This "Life Island" was moderately effective but severely restricted patient activity.

Laminar air flow rooms were originally constructed to assemble space capsules and instruments in a particle-free atmosphere. Cancer researchers applied this technology to patient isolation, and the first prototypes were assembled and successfully operated at the Clinical Center in June of 1968. The laminar air flow rooms utilize plastic sheeting, a "curtain" of flowing air, and a highly efficient air filtration system to greatly increase patient mobility while maintaining very effective isolation and filtration.

However, the NCI alliance with technology was far from over. In April of 1976 the most recent advance in isolation technology was tested in prototype at the Clinical Center—an altered descendant of the biological isolation garments worn by the astronauts of Apollo 11, 12, and 13. This "space suit" packs its own battery-powered air filtration and positive-pressure systems into a minimal 6 pounds, and permits the wearer to leave the hospital for several hours at a time. The fabric is a high-density cotton poplin developed by NASA that permits the outward rush of air but prohibits the influx of particulate matter. The suit restores some elements of a nearly normal, active existence for those patients who must undergo long periods of immune deficiency and laminar air flow room isolation.

The value of the laminar air flow rooms and the space suit is not limited to cancer patients. Burn victims, persons receiving organ transplants, and others on immunosuppressive drugs may benefit from isolation engineering concepts first tested at the Clinical Center.

### Diagnostic Imaging

Early and detailed diagnosis is often the key to effective treatment. A picture or image can truly be worth the proverbial thousand words in helping the physician make such a diagnosis. The Clinical Center has two departments, Diagnostic Radiology and Nuclear Medicine, that are concerned with the production of diagnostic images. Their successes have been so many and varied that it is possible to touch on only a few.

In 1964 Dr. John L. Doppman, now Chief of Diagnostic Radiology, and his associates reported the first successful imaging of the arteries that supply the spinal cord. The technique, known as spinal angiography, has made surgical intervention possible where spinal arterial malformations, lesions, or tumors cause paralysis. The researchers also experimented at this time with embolization (deliberate blockage) of the offending spinal arteries by injecting a clotting agent through the catheter that carries the radiologic contrast medium. Embolization can frequently eliminate the need for subsequent surgery. The technique is also used in cancer patients to decrease the pain caused by untreatable or unresponsive tumors.

Dr. Doppman and his associates in 1968 developed a method for locating the parathyroid, a group of glands, each about the size of a BB pellet, that regulates calcium metabolism. These glands are usually found behind the thyroid. Determining the precise location of a diseased parathyroid is a difficult and frustrating exercise but a critical one for successful surgery. The method developed at the Clinical Center is called "selective venous catheterization." The veins that drain the thyroid gland are sampled by a fluoroscopically directed catheter. The blood samples drawn are tagged by location and subjected to the sensitive radioimmunoassay for the presence of parathyroid hormone. When the levels of the hormones are higher than those in the peripheral blood, this pinpoints the location of the gland or tumor and suggest whether multiple glands are involved in the overproduction of hormones. The technique has been proven nearly 100% accurate in patients with newly diagnosed parathyroid disease.

Researchers in the Nuclear Medicine Department have made similar progress in diagnosing heart and lung disease. In 1976 Dr. Jeffrey S. Borer of the National Heart, Lung, and Blood Institute, Mr. Michael V. Green and Dr. Stephen L. Bacharach of the Department of Nuclear Medicine, and members of the Division of Computer Research and Technology completed the development of radionuclide cineangiography. This technique permits viewing the heart by computer-based movies during and immediately after exercise.

Serum albumin tagged with a radioactive label is injected into a peripheral vein of the patient. A few minutes later a scintillation camera is placed over the patient's chest and begins measuring radioactivity emissions. Data are stored by a computer while the patient is at rest or exercising. The emissions can be displayed simultaneously as a motion picture and as a time-activity curve indicating precise changes in ventricular volume with time.

Using this method the investigators have been able to detect coronary artery disease even in patients who have normal cardiac function when at rest. In patients with known disease, researchers have been able to assess the severity of impairment and to evaluate the effects of therapy. The technique causes little discomfort, offers less risk than cardiac catheterization, and unlike catheterization, can be performed during exercise.

In 1977, using similar techniques, the team at Nuclear Medicine, NHLBI, and Dr. Bruce R. Line of the Division of Computer Research and Technology completed the development of pulmonary scintigraphy, which visually and graphically displays the functions of specific regions of diseased lung in patients affected by pulmonary fibrosis, emphysema, and other lung diseases.

The patient's air supply is tagged with radioactive xenon as the patient breathes from a spirometer. At the same time the pulmonary blood supply is labeled by an injection of technecium-macroaggregated albumin. The labeled albumin particles are larger than the pulmonary capillaries and are temporarily trapped there during measurement.

Gamma rays emitted by the tracers are then measured during respiration by a gamma camera that is placed behind the patient's chair. The tracer activity is visualized and measured by imaging equipment linked to a computer. The computer then constructs pictures that visualize from 1,200 to 1,500 regions in the lung and identifies any diseased area. The information can also be used to determine whether the problem is linked to air flow or pulmonary blood flow.

Ultrasound, a different physical technique, utilizes high-frequency sound waves that are reflected by varying tissue densities and shapes revealing the body's internal structure and form.

Ultrasound has two major advantages over X-rays in noninvasive visualization. First, it is capable of visualizing soft tissues without the physician having to resort to injecting "tagged" contrast mediums, which can be hazardous. Second, while X-rays are known to cause cellular and tissue damage, ultrasound appears to be safe at the levels of intensity used in the existing equipment. The Diagnostic Radiology Department has made some very real contributions to the technology of ultrasound, many of them as recently as this year.

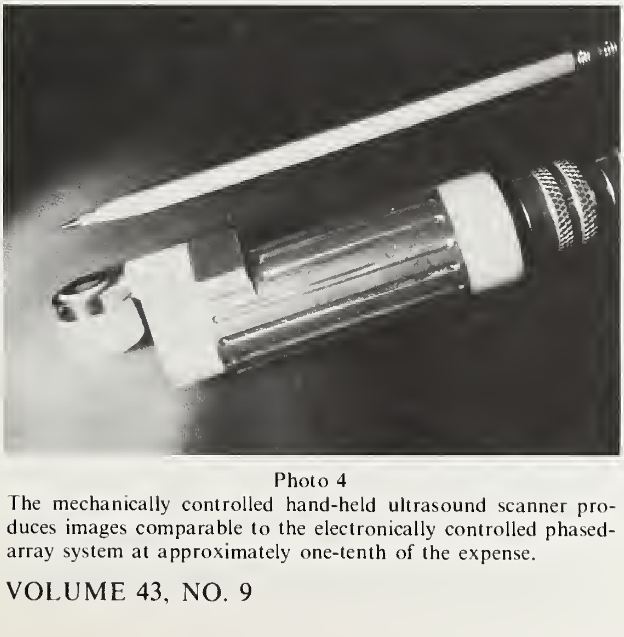

Photo 4
The mechanically controlled hand-held ultrasound scanner produces images comparable to the electronically controlled phased-array system at approximately one-tenth of the expense.

The first generation of ultrasound scanners were somewhat awkward mechanically. The images they produced were of limited value because vibration and lack of control destroyed much of the image quality.

The second generation devices, called "phased array," used sophisticated electronics to compensate for these earlier drawbacks. While they gave a very good image, their price was quite high, approaching $100,000 per unit.

The mechanically controlled ultrasound scanner developed by Dr. Thomas H. Shawker of Diagnostic Radiology and Mr. William Schuette of the Division of Research Services produces images comparable to the phased-array systems at approximately one-tenth the expense. This is a real-time scanner, which gives a continuous "fluoroscopic" image.

Vibration from the hand-held motor that drives the scanning head was nullified by giving the same motor an equally demanding and necessary task to perform—in the opposite direction—namely to power a position feedback control system. The two torques cancel each other out thus producing zero vibration.

The investigators have been able to further enhance image quality by integrating their scanner to operate "in synch" with television hardware. For many reasons television is the ideal means to both display and store ultrasound-generated images. The Clinical Center researchers use a TV camera to record the position of the scanner on the patient's body on the same videotape that records the ultrasound image, thereby creating a third dimension for diagnostic purposes.

### Ambulatory Care Research Facility

A new 13-story Ambulatory Care Research Facility (ACRF) is being constructed to expand and strengthen the combined laboratory and patient care programs of the Clinical Center.

The new facility will provide space for the hospital's rapidly expanding outpatient program. This program, in concert with developments throughout the health care field, is based on the achievements during the past few decades that have made it possible to identify many individuals with early stages of disease. The ACRF will provide an optimum environment to care for and study outpatients, yet it will retain the same proximity between clinical and basic scientists that has successfully promoted medical inquiry.

# GETTING TOGETHER – JUST FOR THE HEALTH OF IT

Based on a successful beginning last year, five major statewide health organizations are again pooling their resources in a continuing effort to provide information people can use to improve their personal "lifestyle."

Last September, under the umbrella name of "The Lifestyle Council of Connecticut," the five agencies launched a multi-media public awareness campaign designed to draw attention to the major factors which a person can control to increase chances of living a healthier, longer life.

Emphasis is placed on proper eating habits, encouragement to stop smoking, exercise, learning to cope with stress and blood pressure awareness.

Governor Grasso has again designated September LIFESTYLE AWARENESS MONTH, and the Council, using the theme "Put A Little Health In Your Life," is making available six easy-to-read, simple-to-follow folders which will be sent free to anyone requesting them.

In addition, health experts from each of the agencies will appear on radio and TV news and public affairs programs during the month to discuss the subjects both individually and collectively. We are certain that all media will again fully support the campaign.

Many of you helped us last year and we hope you will repeat that fine cooperation.

The key to the success of the Council's goal is distribution and you are in a vital position to help by your willingness to place copies of these folders in your waiting room.

Please have someone write requesting folders on Exercise, Nutrition, High Blood Pressure, Stress, Stop Smoking and Lifestyle for use at your location.

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**Lifestyle Council**
**of Connecticut**

# The Treatment of Primary Breast Cancer: Management of Local Disease

SPONSORED BY THE NATIONAL CANCER INSTITUTE

Assisted by the Office for Medical Applications of Research, NIH

## Introduction

The National Institutes of Health "consensus development" program is a formal process that greatly expands the research community's role in readying research findings for health use. Consensus development is a special type of technology assessment which serves as an essential preliminary step before technology transfer.

The NIH proposed such a program several years ago and now the process is gathering momentum as research community support grows. Some important characteristics of the consensus development process at NIH are that it:

Adds to (but doesn't replace) traditional research publication in the open literature;

- Focuses primarily on clinically relevant research and the readiness of certain important findings to be put to use in health care or regulation. (Important scientific issues must be involved.);
- Involves research assessments that, nevertheless, may take into account not only efficacy and safety, but ethical, legal, and cost implications as appropriate;
- Involves a formal, public hearing, at which all pertinent viewpoints are heard; and
- Includes a preparation of a hearing record, including a summary of recommendations and conclusions, which is disseminated to research and practicing communities and the public. These summaries also include differing views, in order to present the whole picture.

In September 1977, the NIH and its National Cancer Institute (NCI) sponsored the first consensus development conference on mass breast cancer screening, including mammography. A panel of scientists, practitioners, lawyers, ethicists, and consumers produced a list of conclusions and recommendations about screening, a number of which later were adopted by the NCI. Since that meeting, NIH has shared in sponsoring more than a dozen consensus development conferences on subjects ranging from surgical treatment of obese patients to the availability of insect sting kits for nonphysicians. More than 24 conferences already are planned for 1979.

In line with the Department of Health, Education, and Welfare's overall technology assessment effort, the Office for Medical Applications of Research (OMAR) was formally established in October 1978 within the Office of the Director, NIH. The prime responsibilities of OMAR are to aid and coordinate the efforts of the constituent Institutes in the process of consensus development. OMAR improves the translation of the results of research and development into information that can be used effectively in the practice of medicine and public health.

The 95th Congress, recognizing the growing importance of technology assessment, passed legislation creating a National Center for Health Care Technology (NCHCT) within DHEW. The Center's role is to undertake and support comprehensive technology assessments taking into account the safety, effectiveness, and cost effectiveness, and social, ethical, and economic impact of health care technologies. As the NCHCT generally concentrates on the cost-effectiveness and regulatory aspects of assessment, OMAR will continue to offer technical expertise and other support in this joint effort. In addition, the congressional Office of Technology Assessment will be working in concert with OMAR and the NCHCT, collecting and disseminating important information about various technologies.

Copies of booklet "NIH Consensus Development Conferences: Summaries from 1977-78," may be obtained from the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205. Copies of 1979 individual conferences are also available.

A Consensus Development Conference on "The Treatment of Primary Breast Cancer: Management of Local Disease" was held at the National Institutes of Health on June 5, 1979. The purpose of the conference was to address the following question:

*Question:*

Are there clinical alternatives to radical mastectomy which minimize patient morbidity and do not decrease a patient's survival potential?

The NIH consensus development program brings together practicing physicians, biomedical research scientists, consumers, and others in an effort to reach general agreement on the safety and efficacy of a medical technology, whether it be a drug, device or medical or surgical procedure.

At the treatment of primary breast cancer meeting, three broad categories of surgical techniques were discussed:

- Radical mastectomy
- Total mastectomy which removes axillary lymph nodes, but preserves the pectoralis muscles
- Lesser surgical procedures such as segmental mastectomy with or without radiotherapy

There was also discussion of radiotherapy as a primary treatment of local breast cancer.

The Halsted radical mastectomy initially introduced for locally advanced breast cancer has been the traditional treatment for the past 80 years. Selection in the past appears to have been based on this tradition rather than tailored to a patient's stage of disease or histologic type. As breast cancer has been diagnosed with greater frequency in its earlier stages (Stage I and Stage II), a major question has been posed to the medical community as to whether this "standard," developed at a time when most women had not been diagnosed until they had extensive local disease, needs to be changed.

There were a variety of surgical options to the Halsted radical mastectomy discussed by the panel. The data that have been generated in several series indicate that a total mastectomy with axillary dissection can be considered as a satisfactory alternative to the Halsted radical for those women with Stage I and Stage II disease. The axillary dissection in this procedure is done for staging purposes as well as for therapeutic benefit.

It was the consensus of the panel that a procedure which preserves the pectoral muscles, i.e., a total mastectomy with axillary dissection, provides equivalent benefit to women who have Stage I and selected Stage II breast cancer. Therefore, total mastectomy with axillary dissection should be recognized as the current treatment standard.

It was also the consensus that a two-step procedure should be done in most cases, i.e., a diagnostic biopsy should be studied by permanent histologic sections before definitive therapeutic alternatives are discussed with the patient.

It was the consensus of this panel that the question of postoperative radiotherapy is moot pending further results of adjuvant clinical trials. Lesser surgical procedures such as segmental mastectomy with or without radiotherapy were discussed. Segmental mastectomy poses the problem of leaving residual breast tissue. The early data presented by Dr. Umberto Veronesi from the National Cancer Institute of Milano, Italy indicate that the residual breast tissue that remains after segmental resection and postoperative radiation does not appear to harbor clinically significant breast cancer. The length of patient follow-up of this trial is approximately four years.

Primary radiation therapy provides two alternatives, either administered in addition to a minimal surgical procedure, or as a single mode of therapy. The trials utilizing primary radiation therapy and the trials dealing with segmental mastectomy are in a stage which is too early to allow determination of survival benefits, but control of local recurrence appears to be similar to current surgical procedures. The trials that explore the question of lesser surgical procedures and those trials exploring alternate modalities to surgery warrant further follow-up and enthusiastic support. These studies should also help to answer the question of the clinical significance of multifocal disease.

Specifically, the panel supported further clinical investigation into the roles of segmental mastectomy and primary radiotherapy. The National Surgical Adjuvant Breast Project (NSABP) protocol was endorsed in regard to answering the question about the effectiveness of lesser surgical procedures in women with Stage I and Stage II carcinoma of the breast. These ongoing clinical trials, because of their exciting preliminary results, warrant support both from patients and physicians so that the continuing search for the optimal patient treatment can progress to the point of maximal patient survival and minimal patient morbidity.

Members of the Consensus Development Panel were: John Moxley, III, M.D., University of California, La Jolla, California, Chairman; John R. Durant, M.D., University of Alabama in Birmingham; Bernard Fisher, M.D., University of Pittsburgh, Pittsburgh; Samuel Hellman, M.D., Harvard Medical School, Boston; Mrs. Rose Kushner, Breast Cancer Advisory Center, Kensington, MD; Bernard Pierquin, M.D., Universitaire Henri Mondor, France; Jerome Urban, M.D., Memorial Sloan Kettering Cancer Center, New York; Umberto Veronesi, M.D., Instituto Nazionale per le Studio e la Cura Dei Tumori, Italy; Joseph C. Allegra, M.D., Jane Henney, M.D., and Franco Muggia, M.D., National Cancer Institute.

# Connecticut's Peer Review Immunity Statute:

## A Legislative History of P.A. 76-413

ROBERT J. BRUNELL, M.A.

Connecticut's Peer Review Immunity Statute, CGS 38-19a-d, is recognized by those knowledgeable in the insurance field as one of the strongest in the nation, covering a multitude of different kinds of professional peer review activities, and giving strong legal support and protection to the frank, open discussions and freewheeling hypothesizing that characterize a confidential, but authentic search for truth in a sea of complex details and circumstances of patient care. The purpose of such committees may be quality of care evaluation, utilization review, cost-control, renewal of privileges, continuing education, malpractice review, complaint-investigation, or still others. These purposes are frustrated if fear of future litigation or liability hampers the free expression and interchange among professionals who are searching for the truth that can build future excellence on the well-examined fragments of past failure. The continued integrity of this process is essential to the progress of patient-care and of medical knowledge.

As may be expected, the Peer Review Immunity Statute comes under occasional attack in the courts by plaintiffs' attorneys who seek a shortcut in constructing a chain of evidence in support of their allegations, or who seek to supplement a dearth of facts and documents with the heady wine of hypothesis. It has been contended that the word "opinions" in the statute should be narrowly construed to permit discovery of the documentary or factual products of these committees' deliberations. Since the word "opinions" had been inserted in Section d just before the bill's passage, in place of "proceedings and records," doubt as to the legislative intent was raised with respect to such immunity from discovery. In this respect, the statute has seldom been interpreted by the courts, and has never been subject to appellate review.

The history of Connecticut's Peer Review Immunity Statute (Public Act 76-413) begins in the 1975 session of the State Legislature, when Senate Bill 776 received support from the Connecticut State Medical Society, the Connecticut Hospital Association, and the Hartford County PSRO (Professional Standards and Review Organization). There was no opposition. The bill received a joint favorable report, came up on the Senate floor May 19, 1975, and was recommitted to the Public Health and Safety Committee without comment and without objection. Neither Senator Lieberman (who asked for recommittal) nor his Administrative Assistant Steve Heintz later remembered why the bill had been killed.[1]

Between the 1975 and 1976 sessions, an Interim Study Subcommittee Regarding Medical Malpractice, co-chaired by Senator Joseph Flynn and Rep. James Palmieri of the Insurance and Real Estate Committee, met and produced a number of bills, one of which was similar to the old S.B. 776. It made reference to *"proceedings and records"* not being "subject to discovery or introduction into evidence in any civil action against a health care provider arising out of the matters which are subject to evaluation and review by such [peer review] committee." The bill went on to specify that "information, documents or records otherwise available from original sources shall not be construed as immune from discovery or use . . . merely because they were presented during the proceedings of such [peer review] committee."[2] (See Exhibit 1)

This bill was raised by the Committee as House Bill 5826. A similar, but partial bill was also raised by the Committee on Public Health and Safety as S.B. 56. S.B. 56 was heard on January 21, 1976 and supported

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**EXHIBIT 1**

Sec. 4 of H.B. 5826, 1976 Session
Connecticut General Assembly
(File 399)

Section 4. The proceedings and records of a medical review committee shall not be subject to discovery or introduction into evidence in any civil action against a health care provider arising out of the matters which are subject to evaluation and review by such committee, and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to any evidence or other matters produced or presented during the proceedings or as to any findings, recommendations or evaluations, opinions, or other actions of such committees or any members thereof. Information, documents, or records otherwise available from original sources shall not be construed as immune from discovery or use in any such action merely because they were presented during the proceedings of such committee, nor shall any person who testifies before such committee or who is a member thereof be prevented from testifying as to matters within his knowledge, but such witness shall not be asked about his testimony before such committee or about opinions formed by him as a result of such hearings.

STATEMENT OF PURPOSE: To provide immunity from civil liability for any member of a medical review committee and any witness appearing before such committee for any action taken by such committee, and to further provide that all proceedings and records of such committee shall be confidential.

by CSMS, CHA and the State Department of Health. There was no objection expressed. H.B. 5826 was heard on March 10, 1976, and was endorsed in principle by Attorney Maxwell Heiman, representing the Board of Governors of the American Bar Association, whose only objection was to the prohibition of a peer review committee member-physician's testifying about his own role in the Committee. It was feared that there would be no way of knowing if a doctor had testified one way in the committee, and perhaps a different way in a litigation. The bill was also characterized by Richard Silver, a plaintiff's attorney, as an "excellent . . . model bill," but who cautioned that hospital incident reports should be construed as original source documents, and not privileged by reason of having been introduced in a peer review committee.[3]

Substitute Senate Bill 56, without further change, received a joint favorable report and proceeded to the floor of the Senate where on March 20, 1976 it was amended to incorporate H.B. 5826, and was moved to the consent calendar. On April 21, 1976, sS.B. 56 came up in the House, where it was adopted with Senate Amendment Schedule A; and a second amendment, House Amendment Schedule A (inserting "optometry") was also adopted. On April 28, 1976, sS.B. 56 came up in the Senate again, where House Amendment Schedule A was rejected, and the bill was sent to a conference committee.

At this point, the bill still included the words "proceedings and records" in Section 4, and *not* "opinions."

The conference committee met, and the bill next came up in the House on May 3, 1976, which adopted the conference committee recommendation to reject both House Amendment Schedule A and Senate Amendment Schedule A, and to insert House Amendment Schedule B instead, which substituted the word "opinions" for "proceedings and records." Representative Healey of the 72nd District summarized the report of the conference committee as follows:

> "Mr. Speaker, House "B" recommended by the Committee on Conference as to Sections 1, 2, and 3, is identical to your file No. 399 (sS.B. 56).
>
> "The difference between House "B" and file No. 399 has to do with Section 4. Section 4 gave many of us, particularly in the House, a great deal of technical problems because it would appear on a reading of Section 4 to create a method whereby certain evidence could be washed through a Peer Review group and thereby be immunized from utilization in any other proceedings. What House "B" does is insert a new Section 4 which restricts this to the opinions of the Medical review committee—that no person who is in attendance at a meeting of such committee shall be permitted or required to testify in civil actions as to any opinions of said committee. It makes it crystal clear that the evidence itself has not been surrounded with the immunity."[4]

The amended bill passed by a vote of 135-0 following this clarification.

The Senate gave final passage to the bill in this form the next day, May 4, 1976, without objection. (See Exhibit 2: Sec. 38-19d) (Optometrists were included by a later technical amendment P.A. 435, Sec. 80, 82.)

Although for a long time, the reason for this last

## EXHIBIT 2

### CHAPTER 675a
### PEER REVIEW AND MALPRACTICE SCREENING PANEL

Sec. 38-19a. (Formerly Sec. 52-197a). Peer review immunity. Opinions not subject to discovery. (a) For the purposes of this section:

(i) "Health care provider" means any person, corporation, facility or institution licensed by this state to provide health care or professional services, or an officer, employee or agent thereof acting in the course and scope of his employment.

(ii) "Peer review" means the procedure for evaluation by health care professionals of the quality and efficiency of services ordered or performed by other health care professionals, including practice analysis, inpatient hospital and extended care facility utilization review, medical audit, ambulatory care review and claims review.

(iii) "Professional society" includes medical, psychological, nursing, dental, natureopathic, osteopathic, optometric, pharmaceutical, chiropractic and podiatric organizations having as members at least a majority of the eligible licentiates in the area or health care facility or agency served by the particular society.

(iv) "Medical review committee" shall include any committee of a state or local professional society or a committee of any health care institution established pursuant to written bylaws, and any utilization review committee established pursuant to Public Law 89-97, and a professional standards review organization or a statewide professional standards review council, established pursuant to Public Law 92-603, engaging in peer review, to gather and review information relating to the care and treatment of patients for the purposes of (1) evaluating and improving the quality of health care rendered; (2) reducing morbidity or mortality; or (3) establishing and enforcing guidelines designed to keep within reasonable bounds the cost of health care. It shall also mean any hospital board or committee reviewing the professional qualifications or activities of its medical staff or applicants for admission thereto.

(b) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any person who provides testimony, information, records, documents, reports, proceedings, minutes or conclusions to any hospital, hospital medical staff, professional society, medical or dental school, professional licensing board or medical review committee when such communication is intended to aid in the evaluation of the qualifications, fitness or character of a health care provider and does not represent as true any matter not reasonably believed to be true.

(c) There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any member of a medical review committee for any act or proceeding undertaken or performed within the scope of any such committee's functions provided that such member has taken action or made recommendations without malice and in the reasonable belief that the act or recommendation was warranted.

(d) The opinions of a medical review committee shall not be subject to discovery or introduction into evidence in any civil action for or against a health care provider arising out of the matters which are subject to evaluation and review by such committee, and no person who was in attendance at a meeting of such committee shall be permitted or required to testify in any such civil action as to any opinions of said committee presented during the proceedings.

(P.A. 76-413, S. 1—4; 76-435, S. 80, 82.)

minute change to "opinions" in Section 4 appeared to be inexplicable, this analysis makes it clear that the legislative intent for the change was to resolve objections involving the feared laundering of original source documents through peer review committees, thus making them immune from discovery in later civil actions. Such chicanery, of course, was never the intent of the bill's supporters, who felt that the statement in Sec. 4, of H.B. 5826, (See Exhibit 2, sentence 2) later sS.B. 56, fully covered this potential problem, as did the Interim Subcommittee, and also the similar language of peer review immunity statutes in other states.[5]

It should be likewise clear that the word "opinions," in the context of Rep. Healey's remarks, includes a peer review group's *own* proceedings, findings, testimony, and the records of its *own* proceedings and decisions. It is this immunity that is necessary to preserve the integrity of the peer review process, not the shielding of original source documents from civil litigants and their counsel.

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# Liability of Hospital Staff Committees

EDWARD E. HOLLOWELL, J.D.

In the somewhat frenetic outpouring of professional literature prompted by the mushrooming of new theories of liability in medical malpractice cases, one potential hazard has gone virtually unnoticed.

For every physician who is found liable for an act of malpractice in the hospital setting, there is a group of three or five or some number of other physicians who are also potential defendants: the members of the credentials committee that recommended approval of the application for privileges, or the members of the quality assurance committee that permitted flagrant practices to go on, or both.

Does a physician, by serving as a member of various hospital staff committees risk potential liability in the performance of those duties? The answer must be "yes." There is always potential liability in undertaking any activity that affects other persons. The liability attaches if there is a negligent act or failure to act that results in injury.

**The real question is, "how great is the risk?" This article attempts to measure it.**

The expansion of liability of entities beyond the treating physician can be traced to the case of *Darling v. Charleston Community Memorial Hospital.*[1] The court allowed recovery against the hospital because there had been a failure to intervene despite obvious indications of malpractice. Perhaps the most discussion-provoking case since *Darling* is the *Corleto v. Shore Memorial Hospital* decision,[2] where a trial court judge, ruling on a motion to dismiss the complaint as to certain defendants, held that the medical staff could be sued as an entity, and indicated that each member of the staff could have been sued individually.

The case law since *Darling* has placed three specific duties upon hospitals in regard to the activities of physicians using their facilities:

- Physicians must not be permitted to violate rules established by the medical staff;[3]
- The hospital must formulate rules to ensure patient safety;[4]
- The hospital must supervise the selection and activities of staff physicians.[5]

The actual holding of *Darling*, however, was that the hospital had a duty, through the medical staff, to supervise the specific treatment recommended by the physician. So most courts have rejected the basic premise of *Darling,*[6] but they have adopted the implication therein that the hospital has a duty to investigate and review the competence of physicians who its facilities. This includes the duty to use reasonable care in the granting of staff privileges, and a duty to terminate or limit staff privileges once the incompetence of a physician has become known.[7] *Corleto* is an example of the theory of corporate negligence being carried to the extreme.[8]

**The significance of this to the individual physician is that implicit in every case since *Darling* is the potential liability of those individuals who undertake evaluation of professional colleagues.**

The only practical method for determining competence available to a governing board is to rely upon a credentials committee or a peer group review committee of the medical staff. This practical necessity is perhaps both cause and effect of the requirement imposed by the Joint Commission on the Accreditation of Hospitals (JCAH) and state law requirements that, in fact or effect, make medical staff committees the agents of the governing board in review of the quality of the physicians' work.[9]

But liability will be imposed, if at all, on the basis of some act, or failure to act, by the individual(s) involved. Agents of a corporation or other legal entity are personally liable if they fail to carry out or

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**"Courts are expanding the potential liability of committee members, staff members, and members of governing boards. Plaintiffs' attorneys are more than willing to provide the opportunity for such expansion."**

negligently carry out a duty owned to an injured party. The individual member of the committee involved is, of course, in the most vulnerable position. If there is evidence that the treating physician was, or should have been, known to be incompetent, such evidence would certainly be most damning against the physicians who had the first opportunity and responsibility to make that determination. It is these physicians who would have the most immediate contact with the incompetent physician, and the best opportunity to obtain knowledge of professional fitness.

Each link along the chain of responsibility—committee to full medical staff to governing board—reduces the degree of personal involvement and thereby makes the possibility of personal liability more remote. The result, of course, is that courts may tend to find new or expanded theories to impose corporate liability on the governing bodies. That is the immediate lesson of *Darling* and its progeny. But the root cause of such liability is negligence by one or more individuals in the process of evaluation.

From the standpoint of the person injured by a wrongful act, the relationship of the wrongdoer to a superior, be it employer, medical staff, governing board or whatever, is immaterial. The liability of the individual wrongdoer is based on the common-law obligation to act so as not to cause injury by a breach of duty to the victim.[10]

The stated purpose of this article was to assess the degree of risk to a physician serving as a member of a staff committee that evaluates peer competence. The foregoing analysis is intended to make this point: courts are expanding the potential liability of committee members, staff members, and members of governing boards. Plaintiffs' attorneys are more than willing to provide the opportunity for such expansion. Such holdings, particularly as applied to individual committee members, have a solid foundation in well settled common law principles. The only real surprise may be that such attempts to obtain additional sources for recovery have been so long in coming.

The assessment must be that significant potential liability does exist. The degree of risk is directly proportional to the degree of negligence on the part of the individual committee member. Both the diligent and the lackadaisical risk being named as defendants. That risk cannot be eliminated. The risk of suffering a loss, however, is minimal for the careful and perhaps staggering for the careless.

**The lesson to be learned is this:** The physician who serves on any committee responsible for evaluation of qualifications or practices should:

- Investigate thoroughly;
- Insist that records of the decisions of the committee and the facts upon which those decisions are based are recorded;
- Be sure that the objection is made a matter of record in those instances where the physician disagrees with the decision of the committee;
- Be certain that the individual professional liability insurance policy covers committee work;
- Urge that the hospital itself carry liability coverage against actions of individual physicians and the medical staff as a whole; and
- Above all, treat these matters with the care their potential danger warrants.

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3. *Penn Tanker Co. v. U.S.*, 310 F. Supp. 613 (S.D. Tex. 1970)
4. *Tonsic v. Wagner*, 220 Pa. Super. 468; 289 A. 2d 138 (1972)
5. *Mitchell County Hospital Authority v. Joines*, 229 Ga. 140, 189 S.E. 2d 412 (1972)
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# Quality Assurance Monitoring and Quality Assurance Programs: A System for Improving Patient Care

MARVIN GARRELL, M.D.

**ABSTRACT—Quality assurance monitoring must be keyed in the hospital to identify critical monitoring parameters to assess quality of care. A computer program is described that assists in this process called quality assurance monitoring (QAM). The same process is used to measure the change that completes the circle of quality assurance.**

Discovering and implementing improved patient care study methods have been evolving since the 1912 efforts of E.A. Codman, M.D., attending surgeon of the Massachusetts General Hospital[1]. He concerned himself with outcome of surgical procedures and set in place a system of patient recall to discover whether a particular operation had maintained a person with continuing favorable outcome. In the last five years, we have witnessed similar efforts by the Joint Commission on Accreditation of Hospitals (JCAH) and Professional Standards Review Organizations (PSRO). Their current methods have plateaued within most hospitals, to evolve about the principal diagnosis or operation groups, and usually review annually only about 12% of the patient census in an average short term hospital. Since the obligation to provide quality care extends to all the patients, the question immediately arises of how to enlarge the numbers reviewed. The state of the art that now exists appears to restrict the quality assessment process. Methods emphasizing identification of "deficiencies" for which corrective action must be taken against individual physicians do not recognize that 80% of deficits are the result of performance inefficiency and institutional sluggishness, rather than medical knowledge ignorance.

It has been apparent to the physician staff of St. Vincent's Medical Center since 1965 that a recurrent monitoring technique is necessary if all the patients are to be reviewed on a continuing basis. It has also been apparent to this same staff that based on statistical probability and review experience any individual physician performance deficit in many instances may occur with any other physician given the same set of circumstances. Only by looking at large groups of patients and instituting hospital-wide change is it probable that care will be improved in sufficient magnitude to be worth the effort. Rascal hunting is a costly futile effort if this remains the primary effort. Thus, there remains the development of the skill to select measurable monitoring parameters for patient care. These parameters can be in turn sorted into meaningful profiles which can then be assessed and utilized for educational links and resulting improvement. The systematic application by remedial measures closes the loop of quality assurance.

Since 1965, St. Vincent's Medical Center has relied on its membership as a PAS hospital for assistance in the task. The Commission on Professional and Hospital Activities has designed a computer program entitled the Quality Assurance Monitor (QAM) and this has been utilized at St. Vincent's. An "in depth" study of the care of all the patients on a diagnosis specific or operative basis is an almost impossible task. The volume of work is overwhelming and 40% of the patients fall into diagnosis whose frequency is too low for valid determinations of patterns of care.

QAM groups patients for monitoring as follows:

a. Monitoring the basic care of all the patients (e.g.

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admission blood pressure, weight, hemogram, urinalysis, blood sugar, BUN, pre-op EKG)

b. Monitoring certain parameters of management (e.g. diuretics, cardioregulators, antibiotics, blood, anxiolytics, neuroleptics.)

c. Monitoring diagnosis or operation specific groups by critical elements (e.g. justification for admission, mortality, abnormal tissue, essential management, essential investigation, essential treatment, validation of diagnosis). For most individual diseases or individual operations the key elements of care for quality assurance review can be limited to an arbitrary six sensitive monitoring parameters[2].

The QAM program is continuous. The trained computer abstractors learn through experience to search the medical record for the key monitoring parameters to validate disease and operation. When not evident, the physician is queried and a performance or knowledge deficit is subject to correction and patient care improvement. The computer reports subsequently the medical records by grouping and those which fail the quality screen are computer flagged for review by the health record analyst by current accepted standards. Each calendar quarter, 1,000 monitoring parameters are computer reviewed. Some of the care of all of the patients is monitored all the time[3]. This monitoring system signals disease, operations, or departmental groups requiring indepth medical care evaluation audits. The skill to select these sensitive monitoring parameters has been organized by CPHA with the assistance of physician representatives from the major organized medical societies. (e.g. ACP, ACS, AAFP, AAP, etc.) Little time is spent in collecting "orphan data".[4]

Each quarter serial display of these monitoring parameters will signal change in performance. Two simple examples from QAM monitoring illustrates this process and graphically monitored positive change at St. Vincent's:

1. Lower extremity phlebitis: Validation of diagnosis shall be present 100% of the time either through venography or phlesmograph or ultrasound." In the time period of April, May, and June 1977 a total of 10 patients were diagnosed phlebitis of which only 2 had venograms and 1 of which was normal. In the period July, August, and September 1978 a total of 15 patients were diagnosed phlebitis. Thirteen had venograms of which 5 were normal.

   These very carefully selected parameters revealed that many patients were diagnosed phlebitis by history and physical examination and not investigation. After several multidiscipline conferences venography in the absence of the other modalities became accepted. The final diagnosis of phlebitis became less frequent, heparin less used, and less hospital patient days consumed.

2. "All hospitalized patients shall be weighed to monitor metabolism, edema states, and medication dosages." 1975, 25% weighed. 1978, 86% weighed. Accomplished through buying more scales and making a nurse practice policy that automatically includes weighing of patients receiving digoxin and diuretics, as well as on admission.

Our society wishes to be assured that a hospital and its physicians are pursuing excellence. QAM is an important step in looking at performance. What steps that are then necessary for change must then be taken. Change must be measured. If the change is positive—quality assurance is in control.

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# Polio, Politics, Publicity, and Duplicity: Ethical Aspects in the Development of the Salk Vaccine

## ALLAN M. BRANDT

This paper is an historical account of the discovery, testing, and early distribution of the Salk polio vaccine. The discovery posed fundamental dilemmas of medical research, pharmaceutical production, and public health. This paper assesses the ethical problems which arose, and examines critically their resolution.

The National Foundation for Infantile Paralysis (March of Dimes) financed and directed the discovery of the vaccine, subsequent field trials, and early distribution. The Foundation's role is analyzed with special attention to the conflicts between its philanthropic and scientific functions.

The great public demand which the discovery of the vaccine generated created a need for federal control which was only partly met. The federal government did not have sufficient institutional and legal mechanisms to assure the safety of the vaccine and protect the public. This discussion illustrates the failure of the government to keep pace with medical technology.

The introduction of a new biological pharmaceutical presents a host of medico-ethical dilemmas. The recent debate surrounding the nationwide influenza vaccination program suggests only a few of the multifarious difficulties involved. Each step in the process—from the initial funding for research to the testing, licensing, commercial production, and distribution of the drug—is wrought with serious judgmental considerations of both a medical and moral nature. If one accepts the public welfare as the preeminent value in the discovery and distribution of a new drug, the role of the government is of primary importance.

The history of the Salk polio vaccine is revealing in this regard. The discovery marks an important episode not only in the growth of immunology, but, most significantly, in the history of public health. The demands made upon the government and the government's response to these demands provide critical insights into the recent course of public health in America. This paper will examine the history of the Salk vaccine in light of the ethical judgments involved.[1]

ALLAN M. BRANDT, M. PHIL., Research Associate for the Program on Ethics and Values in Health Care, College of Physicians and Surgeons, Columbia University. He is presently writing a social history of venereal disease in the twentieth century United States.

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[1] Several studies of the development of the Salk vaccine have been written, although none is definitive. The most comprehensive of these is *Breakthrough: The Saga of Jonas Salk* by Richard Carter.(1) Rich in detail, though weak in analysis, this book was particularly helpful in my study. Also recommended are John R. Wilson's *Margin of Safety*(2) and Aaron E. Klein's *Trial By Fury: The Polio Vaccine Controversy*.(3) The definitive medical history of poliomyelitis is *A History of Poliomyelitis* by John R. Paul.(4)

The archives of the National Foundation have unfortunately been closed to researchers. This rich collection of materials contains valuable information pertaining to the development and distribution of the Salk vaccine.

### The National Foundation for Infantile Paralysis

The vaccine discovered by Salk in 1952 marked the culmination of the efforts of the National Foundation for Infantile Paralysis to secure an immunological agent against polio. The Foundation had grown out of efforts to raise funds for Franklin D. Roosevelt's Warm Springs retreat during the Depression. In consultation with public relations firms, Roosevelt's former law partner, Basil O'Connor, organized a series of "President's Birthday Balls" in 1934 with the slogan: "Dance so that others may walk"(3, p. 16). In 1937 Roosevelt announced the formation of the National Foundation for Infantile Paralysis (NFIP) for the purpose of ensuring "that every responsible research agency in this country is adequately financed to carry out investigations into the cause of infantile paralysis and the methods by which it may be prevented."(5) Basil O'Connor became the president of the new organization.

The creation of the Foundation signaled a major new direction in the history of American medical philanthropy. The appeal for funds now utilized sophisticated public relations techniques.(6) Of significance was the dramatic extension of the traditional concept of philanthropy, as the National Foundation now sought funds from everyone, not just the affluent. Radio spots requested that dimes be sent directly to FDR in honor of his birthday on January 30, 1938. More than 2,600,000 dimes "marched" into the White House, inundating the mail room.(3, p. 18) Thus was coined the title "March of Dimes."

The Foundation pioneered in the techniques of modern fund raising with its mass appeals, use of media, public relations, and a corps of volunteers. The unprecedented doorbell campaign—the "Mothers' March on Polio"—began in earnest; the Foundation put its cadres into the streets. Their ability to raise funds, even during the most trying economic circumstances, must be rated remarkable. By the 1950s the National Foundation had developed the perfect form of philanthropy for the burgeoning consumer culture.[2] The concept of philanthropy as consumerism—with donors promised personal benefits—was to a great degree the contribution of the March of Dimes.

Why did poliomyelitis become the rallying point for millions of Americans? One logical answer is, of course, Franklin Roosevelt's personal battle with the disease. Despite FDR's attempts to conceal his infirmity, a new media age made polio the most prominent of diseases. But Roosevelt merely symbolized a more general perception that polio was a peculiarly American malady. More dangerous in affluent nations, polio became America's target although other diseases and medical afflictions were really more common.[3] An increasingly child-oriented society could not tolerate a disease which crippled its young.[4] In addition, the National Foundation had a remarkably powerful influence on the whole direction of American medical research and health care priorities, a topic that demands more attention than is possible here.

There can be little doubt that the Foundation put its funds into the right hands. Through the use of long-term, substantive grants awarded to eminent researchers and institutions, the NFIP insured the continuity of polio research. By 1948 a series of important epidemiological studies had been made under the Foundation's auspices. Most important was the discovery of Drs. John Enders, Thomas Weller, and Frederic Robbins, all of Harvard University, that poliovirus could be cultivated in nonnervous tissue.(4, pp. 369-381; 9) This Nobel Prize-winning discovery virtually assured that a polio vaccine could be produced. A race, with bitter political and personal overtones, ensued.

### Development of the Salk Vaccine

Dr. Jonas Salk began his research on polio immunization in 1951 under a grant from the National Foundation. Within a year he had successfully immunized monkeys in his laboratory at the University of Pittsburgh. Confident that he had found the key to immunization in a killed virus vaccine, Salk proceeded to test his discovery on human subjects. The first of these experiments was conducted on children from the D.T. Watson Home for Crippled Children. Risk was reduced by vaccinating these children, who had already had polio and were thus immune prior to injection. Salk inoculated 43 children with no adverse reactions. He later commented, "When you inoculate children with a polio vaccine, you don't sleep well for two or three months."(1, p. 139)

Salk continued his experiments at the Polk State School, where he again inoculated children with his test vaccine. Unlike the polio victims at the Watson Home, these children, who were mental defectives, had no history of polio and thus much lower antibody titer, significantly increasing the danger of the test. The ethical standards applied here, though in no way unusual in the 1950s, must be questioned. Dr. Tom Rivers, one of the most eminent virologists in the history of modern immunology, in reviewing an experiment similar to Salk's, voiced concern about the morality of such a test:(10, pp. 466-467)

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[2] For a more extended analysis of the implications of consumer culture, see reference 7.

[3] Nations with high standards of sanitation and personal hygiene actually prove to be more susceptible to enteric viral infections such as poliomyelitis (4, pp. 364-365).

[4] For an explanation of attitudes toward children in the postwar era, see reference 8.

> I think that if someone wants to use adults as volunteers to try out a new drug or vaccine, that is perfectly all right, provided that the adult has been told about the nature of the disease he is exposing himself to, has been completely informed about the nature of the agent he is to receive, and has been told the chances for success or failure. . . . An adult can do what he wants, but the same does not hold true for a mentally defective child. Many of these children did not have mommas or poppas, or if they did their mommas didn't give a damn about them.

Fortunately, Salk's confidence in the vaccine was borne out by the results of these initial human tests. But Dr. John R. Paul, in his definitive history of poliomyelitis, pointed out what failure may have entailed:(4, p. 418)

> Had the experiments gone wrong at this point there might have been a tremendous outcry. Some would have called it unnecessarily hasty to use so many subjects all at once. . . . And others would have called it a crime to subject helpless children and adults to this sort of experimentation.

It would seem from this analysis that an experiment on human subjects is ethical if successful, unethical if a failure—a dubious formulation. No government guidelines or requirements for human testing existed at that time.

Salk's success buoyed his faith in the vaccine. In presenting his findings to the medical community, he was, however, more cautious:(11)

> Although the results obtained in these studies can be regarded as encouraging, they should not be interpreted to indicate that a practical vaccine is now at hand. . . . It will now be necessary to establish precisely the limits within which the effects here described can be reproduced with certainty.

The task of establishing the effectiveness and consistency of the new vaccine would not be Salk's alone.

### Planning the Field Trials

By the middle of 1953 the National Foundation had begun devising plans for a mass nationwide trial, the largest of its kind ever attempted. The Foundation established a Vaccine Advisory Committee (VAC) of eminent physicians and researchers headed by Tom Rivers to oversee the field trials. The NFIP's decision to conduct such a field trial meant that serious consideration of other forms of immunization, particularly the attenuated vaccine, no longer was possible.(4, pp. 423-425) The Foundation's position, though clearly understandable in light of the embryonic nature of attenuated vaccine research, sparked controversy and aroused bitterness. From this time onward, criticism of the Salk vaccine would be an indeterminate mixture of scientific judgment and personal animosity.[5]

The National Foundation conducted affairs on a grand scale; the field trials slated for early 1954 were to be no exception. The NFIP with its newly created Vaccine Advisory Committee proceeded to design the trials in a direct, almost autocratic manner. After his initial discovery, Salk found his influence diminishing over subsequent decisions concerning testing, as did a host of other scientific advisers to the Foundation. Basil O'Connor, anxious to move forward with all possible speed within the bounds of safety, pushed the VAC in the singular direction of conducting a definitive test.(10, pp. 495-500)

Scientific advisers clashed over the design of the trials. Originally, the Foundation planned to vaccinate volunteers and compare the rate of paralytic polio among this group to a control group of nonvaccinated children. This format had the advantage of being easy to administer and evaluate, and in addition gave all volunteers the potential benefit of the vaccine. The Vaccine Advisory Committee insisted, however, that a "double-blind" test was necessary to eliminate the socioeconomic bias of the volunteer group and thus provide a scientifically unassailable evaluation. Under this test, half the volunteers would receive vaccine, half placebo.

This decision infuriated the increasingly confident Salk who called the double-blind test a "fetish of orthodoxy. . . ." Salk clearly exposed the ethical dilemma of using a placebo in an impassioned letter to O'Connor:(1, pp. 191-192)

> . . . if we are aware of the fact that the presence of antibody is effective in preventing the experimental disease in animals and in man, then what moral justification can there be for intentionally injecting children with salt solution or some other placebo for the purpose of determining whether or not a procedure that produces antibody formation is effective . . . [?] I would feel that every child who is injected with a placebo and becomes paralyzed will do so at my hands.

Such an experiment, argued Salk, "would make Hippocrates turn over in his grave."

It is not difficult to sympathize with Salk's viewpoint. With a double-blind test the effectiveness of his vaccine would essentially be proven by the contraction of polio among those children who received placebo. But the emotional content of Salk's plea would also seem to indicate the importance of removing the test from the hands of the discoverer. In a sense, Salk favored an early limited distribution of his vaccine as a test for efficiency, not a carefully controlled, scientifically conducted examination. Sure of the safety and effectiveness of his vaccine, he actually jeopardized its full acceptance in the medical community. This is not to question Salk's scientific ethics or his personal morality, but rather to suggest the difficulties of participating in the evaluation of one's own research.

Though the National Foundation took full responsibility for the field trials, the VAC commissioned Dr. Thomas Francis of the University of Michigan to evaluate the trials. Francis, a pioneer in the fields of microbiology and immunology, commanded unquestioned respect in the scientific community. The Foundation assured the University of Michigan ample funds to assist in Francis' evaluation. He demanded complete control of the evaluation—with no outside pressure, timetable, or supervision—and O'Connor agreed to these stipulations. Francis also insisted on an injected control group in at least some states. The decision to have Francis assess the vaccine insured an irreproachable trial.

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[5] See references 1 and 2 for extended discussions of the bitter relationship between Salk and Dr. Albert Sabin of the University of Cincinnati.

Before a trial could be attempted, however, the difficult transition from an experimental, laboratory-produced vaccine to a consistent, commercially manufactured vaccine had to be negotiated. Until commercial laboratories could produce vaccine, all talk of a field trial was really premature. Although the National Foundation contacted five major pharmaceutical companies to produce vaccine for the field trials, a complete draft of the requirements for production did not evolve until early 1954, only several months before the trials began.(1, pp. 207-211) The Vaccine Advisory Committee supervised the shift to commercial production, making two critically important recommendations. First, the Committee required that Salk conduct an initial trial on at least 5000 children using commercially produced vaccine before undertaking nationwide trials. And secondly, *all* commercial vaccine for the field trials had to undergo safety tests in three laboratories—the producers', Salk's, and the U.S. Public Health Service's Division of Biological Control.(12)

The decision to test commercial vaccine in the federally operated lab represents the difficulty of the government's position. The government had no legal role in the trial; no license was required for such an experiment. The Food and Drug Administration only required that the test drug be safe, not necessarily effective.(13) A major medical advance was in the making, with the government's only capacity an essentially extralegal one. Moreover, when it came time for the licensing of the vaccine, the Public Health Service would be in the dark. "We wouldn't know enough about the vaccine and the ins and outs of its manufacture," remarked a Public Health Service official. "We would not be able to act on license applications for months. But the public would want action in hours."(1, p. 209)

With no official role in the testing of the vaccine but badly needing more information, the Public Health Service gladly accepted the functions allocated by the Vaccine Advisory Committee of the National Foundation. Indeed, the Division of Biological Control, under the direction of Dr. William Workman, scrutinized procedures to the point of threatening the trials. Workman and other government officials realized that, although they had no legal sanctions, they had the responsibility of insuring a safe, effective vaccine.(1, p. 208) Moreover, the National Foundation recognized the importance of having the blessing of the Public Health Service before conducting its trials.

### Opposition to the Trials

Scientific opposition to Salk's vaccine remained formidable as the trials approached. Some scientists had difficulty duplicating Salk's inactivation process in their own labs, while others questioned the viability of a killed virus vaccine. Dr. Albert Milzer had been unable to reproduce the Salk vaccine in his laboratory at the University of Chicago. He repeatedly found live virus in the vaccine—an ominous result. Dr. Albert Sabin, at work on an oral, attenuated vaccine, became Salk's chief antagonist. Only one month before the field trial was set to begin, Sabin called the test "premature." Salk and the National Foundation attempted to combat the criticism: "I give every possible assurance I can and that medical science can that the antipolio vaccine will be safe. I will personally be responsible for the vaccine," declared Salk.(14, 15)

More troublesome than this criticism, however, were the continued difficulties of the commercial producers in their attempts to replicate Salk's vaccine *en masse*. Scientists at the Public Health Service's Division of Biological Control harbored serious doubts about the abilities of the manufacturers to produce consistently safe vaccine. This reflected, in part, inexperience in the histopathology of polio.(10, p. 513) But it also revealed a very real production problem. In March 1954, Dr. William Workman suggested that the field trials be postponed:

> I again come to the conclusion that the specifications and minimum requirements . . . are inadequate to assure the reasonable regularity of production of a vaccine of acceptable safety to be used in the field study. Under the circumstances, I cannot escape the feeling that an occasional lot . . . which does pass the test, may actually contain living virus and be unsafe for use. My recommendation is that the proposed field studies be postponed until—(1) specifications and minimum requirements can be revised to give greater assurance of the safety of the final product; (2) it has been shown that the vaccine prepared in accordance with such specifications meets acceptable criteria for safety (1, p. 221).

It should be emphasized, however, that the government had no legal means of postponing the trials. The National Institutes of Health and the National Foundation agreed that, rather than revising the safety tests themselves, companies must produce eleven *consecutive* lots of safe vaccine for any to be acceptable for use. With this agreement, plans proceeded for the field trials.

### The Foundation, the Press, and the Public

Despite the persistent opposition within the scientific community, the National Foundation and the press stimulated public optimism for the vaccine's success. The dual role of the National Foundation—philanthropic and scientific—created tensions. The profusion of positive press releases, essential to fill the Foundation's coffers, jeopardized scientific judgments.(3, pp. 82-85) The National Foundation announced publicly the plans for a mass field trial months before a commercial laboratory had produced any vaccine.(16)

The press played upon the drama of the situation; no medical discovery before or since has been covered as intensively. Beginning in 1953, progress in the vaccine's development was regularly front-page news in the *New York Times*. Press reports were often filled with speculation:(17)

> If the vaccine fulfills the hope that at last a way has been found to cope with poliomyelitis as effectively as public health officers cope with smallpox or typhus, Dr. Salk will have scored one of the greatest triumphs in the history of medicine.

Although Salk and the National Foundation attempted to discourage such optimistic conjecture, Basil O'Connor's euphoria could not be contained. He declared that the development of the vaccine had brought the fight against polio to the "verge of victory."(18) The *New York Times Magazine* called the trials the "climax of a stirring medical drama."(19)

The vaccine's notoriety undermined the control of the scientific community. The public now clamored for the vaccine, making it increasingly difficult for scientists with reservations to resist the demand for mass testing. Sabin's attacks on the vaccine became more personal in nature: "Let us not confuse justifiable optimism with achievement."(20) And Salk's defense became less scientific: "I have the courage of my convictions. I couldn't do it unless I was more critical of myself than others are of me. It is courage based on confidence, not daring, and it's confidence based on experience."(21) Salk continued to announce that he would take "personal responsibility" for the safety of the inoculation—a courageous, if ill-advised stand.(22) The *New York Times* felt qualified to endorse the trials, remarking:(23)

> No matter how important a medical discovery may be, there are always skeptics who try to strip it of importance. We need these skeptics, but sometimes they may be nuisances.

At this point the skeptics were threatening the test. Several states withdrew from cooperation in the trials after Walter Winchell announced on national television and radio that the vaccine "may be a killer."(24)

This is not to argue that the press and public should have no role in a medical discovery, but rather that, in this kind of atmosphere, where public demands and expectations are great, sound scientific judgment may be jeopardized. The Salk vaccine was sold to the public before its safety and efficacy were proven.

The National Foundation must bear some of the responsibility for the public fervor which surrounded the field trials. Perhaps the most objectionable of all the Foundation's pronouncements was that the test was exclusively designed to test the efficiency of the vaccine. According to the Foundation, safety had already been conclusively demonstrated. In light of the production difficulties, this was a particularly bold assertion. The NFIP struck the word "experiment" from its literature; this was a "trial" vaccine, not an "experimental" vaccine. Although the test was conducted on a voluntary basis, the *quality* of informed consent is thus highly questionable.[6]

### Testing and Evaluating the Vaccine

On April 25, 1954 the Vaccine Advisory Committee set up final guidelines, giving its approval for the trials. The United States Public Health Service issued the following statement:(26)

> We believe that the judgment of the Vaccine Advisory Committee is sound and that the National Foundation for Infantile Paralysis is justified in proceeding according to the Committee's recommendations.

The next day the field trials began. With more than 1,800,000 children participating, the trials mark the largest clinical test using human subjects in the history of medical science. No medical experiment ever held such public attention. According to a Gallup Poll conducted in May 1954, 90 percent of the American people knew of the field trials, more than could identify the full name of the President of the United States.(1, p. 268)

The test, conducted in 45 states, used placebo controls in 84 areas and observed, nonvaccinated controls in 127 areas. More than 400,000 children received three injections; about 200,000 of these actually received salt-water placebo injections rather than the test vaccine. Along with blood samples to test antibody titer, Dr. Thomas Francis now had the information needed for a conclusive evaluation of the vaccine.(1, pp. 238-261)

Speculation was rampant concerning the results of the field trials, but Francis promised no announcements until the spring of 1955. He had more than 144 million pieces of information to assemble and review. Some days the Evaluation Center's morning mail filled an entire elevator.(1, p. 255)

A critical problem faced the National Foundation during this interim period while awaiting Francis' report. Without a federal license (which could not be obtained until the vaccine was finally evaluated) and without advance orders, the pharmaceutical companies could not afford to continue to produce vaccine. It was not difficult to foresee a situation in which the vaccine would be found to be safe and effective, and yet there would be no vaccine available for the 1956 polio season. Basil O'Connor, with typical boldness, ordered $9 million worth of vaccine from six pharmaceutical companies—an expensive gamble on the vaccine's approval. Of course, if the Congress had been willing to allocate funds, this risk could have been avoided. But the government seemed content to let the National Foundation carry the ball.

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[6] Parental consent was required for a child to participate in the trial. Excellent essays on informed consent and human testing are contained in reference 25.

On April 12, 1955, the tenth anniversary of Franklin Roosevelt's death, Francis released his evaluation, one of the most comprehensive epidemiological studies ever conducted. According to Francis, the safety of the vaccine was "powerfully affirmed."(27, 28) This is an interesting observation in view of the National Foundation's reluctance to consider the trials a test of safety. Francis found the vaccine 80 to 90 percent effective in placebo-controlled areas, slightly less in observed controlled districts.(28, pp. 15-19) In short, the vaccine appeared to be a tremendous success. The nation celebrated; for many parents, it seemed, the anxious summers were over.

The successful development of the polio shot characterized the Eisenhower years as the moon shot did a later era. The image of the scientist-hero, unhampered by government intervention, held great appeal. The press proclaimed Salk a national demigod, while some colleagues, resentful of all the attention he received, suspected him a demagogue. The vaccine became a perfect cause for an age in which ideology was suspect.[7] The scientific atmosphere of the 1950s was wrought with Cold War overtones. The vaccine, an affirmation of American scientific and technological progress, was viewed as a triumph of the American system. American science, pragmatic and purposeful, demonstrated the continued viability of the promise of American life.

In Washington, Mrs. Olveta Culp Hobby, Eisenhower's Secretary of the Department of Health, Education, and Welfare, signed licenses for six companies to produce vaccine. These companies had, of course, been producing vaccine all along; the licenses gave them authority to distribute it.[8] The National Foundation's vaccination program for school children began immediately, with youngsters who had received placebo during the field trials given top priority. For all intents and purposes this should have been the dramatic conclusion to the conquest of polio. Unfortunately, it was not.

### The Cutter Crisis

On April 26, 1955, two weeks after Francis' Ann Arbor proclamation of safety, five cases of paralytic polio were reported among children who had just received vaccine. All five victims, it was found, had received vaccine from the Cutter Laboratories in California. Surgeon General Leonard Scheele requested that Cutter recall all its vaccine pending an investigation. Remarkably, the government had no power to order the Cutter Labs to withdraw the vaccine, but Cutter readily complied. The infamous "Cutter Incident" would, however, eventually encompass 25 states and Hawaii, 260 cases of polio, and 11 deaths.(1, p. 316)

These cases of polio cast an ominous cloud over the Salk vaccine, the National Foundation, the pharmaceutical companies, and the National Institutes of Health. What had gone wrong with the most rigorously tested drug in medical history? The most obvious cause of the problems was that the careful triplicate testing of the field trials had not been continued for the licensed vaccine.(12, pp. 329-331) Written protocols submitted by the manufacturers to the Division of Biological Control were the only legal requirement. The Division had the right to make spot checks, but did not exercise this option. Moreover, the consistency standards of repeated safe batches which had been devised for the field trials were not required of licensed vaccine. In brief, safety precautions for commercially produced, licensed vaccine fell far short of the guidelines used for the field trials.

During a series of meetings of top virologists and advisers called together by Surgeon General Scheele, it was decided to let the vaccination program continue. But this consensus began to erode quickly. Dr. John Enders, regretting his approval for continuing the program, wrote to Dr. William Sebrell, the Director of the National Institutes of Health:(32)

> I am forced to conclude that active virus might be present in certain finished lots of vaccine prepared by any or all of the manufacturers concerned. I cannot, therefore, longer assert my confidence that the poliomyelitis vaccine now being distributed and injected consists solely of inactivated vaccine and in consequence, of harmless virus.

On May 7, Scheele *requested* that the national vaccination program be suspended pending further studies.

Scientific criticism of the Salk vaccine intensified. In June, Enders and Sabin testified before a House subcommittee investigating the crisis that the vaccination program should be stopped and the licenses withdrawn until safety could be conclusively proven. But they were overruled by an equally eminent group of scientists who expressed confidence in the quality of the vaccine if properly produced.(33)

On June 9, Scheele released a Public Health Service "Technical Report" on the Salk vaccine, an attempt to explain and correct the problems which produced the Cutter crisis. The "white paper," though not a complete whitewash, was carefully written to avoid directing blame:(34)

> The Salk vaccine applies new principles in the production of viral vaccines. The speed of its development, which reflected the increased tempo of all medical research, created problems

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[7] Excellent discussions of political and cultural life in the 1950s are contained in references 29 and 30.

[8] One of the six companies was the Cutter Laboratories of Berkeley, California. The Regional Oral History Office of the University of California at Berkeley recently completed an oral history memoir with individuals from this organization, documenting its involvement with the vaccine(31).

> in biologics control amenable to solution only with the accumulation of knowledge and experience. It is likely that problems of equal complexity will be raised by the development of other new viral vaccines.

This analysis obscured the inadequate preparations made by the Public Health Service for testing the vaccine. Despite the easily predictable demand for the vaccine, the Bureau of Biologics staff remained at only 35, insufficient to carefully scrutinize the commercial production process. Moreover, the protocols required of manufacturers did not provide enough information for proper safety evaluation. The contrast between the careful tripartite testing of the trial vaccine and the testing of the commercial product is a remarkable example of the lackadaisical attitude of the government toward biological control.

The irresponsibility of the Cutter Laboratories must not be overlooked in evaluating the crisis. Repeated difficulties in producing safe vaccine were experienced by the Cutter Labs; 9 out of 27 lots produced had contained live virus and were discarded. Yet Cutter failed to report this inconsistency to the Bureau of Biologics; the company only submitted protocols for batches which passed their safety test.(34) Cutter officials never asked for assistance from NIH or Salk. Their ethical commitment to produce safe vaccine must thus be seriously questioned. But it also must be remembered that they acted entirely within the letter of the law. The NIH had no consistency requirement and did not require reports on discarded vaccine or production difficulties.

The Public Health Service's "white paper" explained the manufacturing problems in terms of inadequate sensitivity of the safety tests:(34, p. 17)

> Each producer had had difficulties in processing and testing materials at various stages of production. Because some lots were obviously unsatisfactory they were not submitted for release, and therefore no protocols on them were submitted by the manufacturers. These experiences showed the need for more sensitive and better controlled testing methods, and for greater attention to the history of consecutive lots.

The Public Health Service revised the minimum requirements for production in light of the Cutter incident, making them mandatory standards. The Division of Biological Control was reorganized, becoming the Division of Biologics Standards with larger facilities and a fourfold increase in staff.

The relationship between the commercial producers and the federal government lay at the heart of the Cutter incident. This association became the target of serious investigations in the days following the tragedy. Victor Haas, the Director of the National Microbiological Institute, a division of NIH, evaluated the government-pharmaceutical connection in a series of memos to Sebrell in May 1955.[9] Haas argued that the responsibility for safety must ultimately rest with the manufacturers, and that the government could not (and should not) participate intensively in the safety testing of biologic products:(35)

> It has been the principle of operation that this intensive participation in what is essentially a part of the manufacturing process, properly should be only a temporary activity for the Laboratory of Biologics Control. Once it has been established that manufacturers can produce safe material (and production experience and field trials of last summer formed the basis for licensing manufacturers for polio vaccine), this principle of operation would assume that periodic plant inspection, knowledge of the capabilities of supervisory personnel, review of protocols, and spot-testing of materials would suffice to assure us of continuing acceptability of any product within the limits imposed by available knowledge and human acceptability to error.

Intensive and continuous testing in government laboratories, Haas believed, would destroy industrial initiative and responsibility. According to his evaluation, more testing and inspection would not have prevented the Cutter incident. This is a dubious assertion, for certainly the manufacturing difficulties experienced by Cutter and the other pharmaceutical companies would have been revealed, raising questions of safety.

Finally, Haas suggested that it would be improper to overreact to the Cutter incident by revising existing standards of control. He ascribed the current fervor to the tremendous publicity which the polio vaccine had generated:(35)

> Had the poliomyelitis vaccine been used on the same quantitative scale that applies to other biologicals and had an incident occurred, there would have been very little attention given it other than by the constituted authorities. The many factors which have gone into creating a demand for a safe and effective poliomyelitis vaccine, which would be available at the earliest possible time, should not force us to abandon careful and sound judgement as to what is the best method for the operation of biological control over the years.

### Ethics, Industry, and the Public Welfare

The Cutter incident exposed the inherent weakness in the argument for governmental laissez-faire with regard to biologics control and pharmaceutical production. The limited role of the federal government clearly reflected the Eisenhower political philosophy. Olveta Culp Hobby eventually lost her job, largely because of the vociferous criticism of her handling of the vaccine program. In addition, the government's action was circumscribed by the miniscule legal powers of the Public Health Service, essentially unrevised since 1902, a time of relatively primitive pharmaceutical production. The government continued to assume that industrial interest in producing a safe product would ensure the public's safety.

In view of the federal government's minor role, the

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[9] These memoranda, marked "confidential," have only recently been opened to researchers as a result of a Freedom of Information suit. They are a highly valuable source for deciphering the government's view of its role in the development of the vaccine(35).

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8-3305 (Y371A)

National Foundation assumed massive responsibilities in the development and distribution of the vaccine. Combining the functions of fund-raising, research, testing, and distribution, the National Foundation often found its multiple roles conflicting. Although well-intentioned, the publicity mill created an atmosphere in which demand threatened to outstrip sound scientific decision making. In such an environment, ethical questions can become obscured. The field trial, for example, though brilliantly engineered and promoted, and meticulously evaluated, lacked truly informed consent.

The ethical aspects involved in the development and distribution of the Salk vaccine are varied and complex, and the historian must be leery of second-guessed, overarched generalizations. But three key issues which demand continued attention emerge. First, testing with human subjects presents a series of problematic considerations, from the suspect use of mentally defective children to the use of healthy, parent-volunteered youngsters. High ethical standards for defining risk-benefit ratios must be exercised in such investigations; use of placebos complicates such assessment. Moreover, informed consent is liable to compromise.(36) Second, the obligation of pharmaceutical companies to manufacture safe products cannot be assumed, especially when pressures to market a new drug become intense. The third point is most striking: the federal government's minimal role in a major scientific advance. Although the government cannot be the final arbiter of ethical medical judgment, it is the only body which can provide a central direction and standard for these practices. By abdicating a more active role, the government invited the possibility for crisis. The Salk episode seems to indicate a less than complete commitment by the government to the public welfare.

In the years since the discovery of the Salk vaccine, the problems of pharmaceutical control have expanded rather than diminished. The capacity of the government has remained limited in overseeing industry. The Government Accounting Office, Congress' investigative arm, recently attacked the lax attitude of the Food and Drug Administration's drug testing.(37, 38) According to the GAO's report, human subjects are exposed to unnecessary risks and the FDA has approved new drugs for public use on the basis of highly questionable data. FDA attempts at self-investigation have proven largely useless.(39) The FDA has failed to enforce its standards and, according to many reports, has served as a lackey to the major pharmaceutical companies.(40) In its mission of public protection, the FDA, by any standards, has proven to be grossly inefficient.

The history of the Salk vaccine, from the initial research through testing and production, speaks clearly to the present. The institutional connections through which a new drug is channeled from laboratory to market remain uncertain, subject to frequent short-circuit. The time between discovery and production has steadily decreased, augmenting the difficulties implicit in regulation. Most importantly, the federal government has failed to keep pace with the rapid innovations in medical and pharmaceutical practice, at great cost to the public welfare.

*Acknowledgements*—I should like to thank Harold Fruchtbaum and Alan Gardner for critiques of earlier drafts of this paper.

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## AMA Urges Increased Federal Funds for 13 Major Health Programs

The American Medical Association has urged Congress to increase funding for 13 programs that "hold the greatest promise for improving our nation's health."

In letters to the chairmen of key Congressional committees, the AMA said it was limiting its recommendations for increased appropriations in fiscal year 1980 because of inflation in the general economy and the need to control deficit spending.

"We are working with Congress to develop legislation that will focus on positive health strategies as well as health program cost reductions," the AMA said.

"The challenge is to act with fiscal constraint and responsibility while making sure our Federal tax dollars are spent in the best possible way."

The AMA recommended that funding be increased beyond President Carter's budget request by $613.4 million, with the largest increase going to the National Institutes of Health ($227.6 million) and health professions education ($143.4 million). More money also was recommended for maternal and child health, family planning, emergency medical services, venereal disease control, immunization, childhood lead-based paint poisoning prevention, health education, mental health, alcoholism, aging, and the Food Drug Administration.

The letter described AMA efforts to restrain costs through the National Commission on the Cost of Medical Care and the Voluntary Effort, and called on Congress and the Administration to continue implementation of the anti-fraud and abuse legislation and the Medicare-Medicaid quality control and management program and to support the Voluntary Effort and the PSRO program.

The AMA also recommended that Congress and the Administration support actions to reduce the high costs caused by excessive Federal regulation, seeking a spending reduction of at least 2 percent annually in operating expenses of all Federal agencies, and support "sunset" plans that would provide for periodic review of Federal spending programs.

# Trends in Certification As It Applies to Licensure

JACKSON W. RIDDLE, M.D., PH.D.

From its inception, medical specialty certification has been voluntary in the United States. Since the establishment of the first nationally recognized medical specialty board in 1916, some physicians have elected to seek formal recognition of their qualifications in their chosen specialty fields by presenting themselves for examination before specialty boards comprised of their professional peers. The definition of each of the specialties and of the educational and other requirements leading to eligibility for board certification have been developed by consensus within the medical profession and, to date, the certification of a medical specialist has remained separate and distinct from licensure by civil authorities, the state medical boards, of those qualified to practice medicine within their jurisdictions.

A committee of the American Board of Medical Specialties recommended recertification in 1940, and only seven years later, in 1947, the American Academy of General Practice started the procession by requiring proof of continuing education in order to maintain good standing.

In 1969, the American Board of Family Practice made recertification a mandatory requirement.

In 1970, the Council on Health Manpower of the American Medical Association recommended that specialty boards develop recertification procedures based on continuing education activities, although they opposed such as a condition to relicensure. The American Board of Medical Specialties adopted, in March, 1973, the position that all boards should have recertification policies. Recertification is now a policy of all 22 medical specialty boards, and 17 have set dates to commence the process. Later, three others, the American Board of Colon and Rectal Surgery, the American Board of Surgery, and the American Board of Thoracic Surgery, made recertification a mandatory requirement. By 1974, the American Board of Internal Medicine administered the first voluntary recertification examination.

Report A of the Board of Trustees of the AMA in 1975 said of certification and licensure:

"One of the concerns in this area is that recertification and relicensure procedures should reflect an evaluation of a physician's performance in delivering patient care, in addition to his knowledge of pertinent subject matter. Examinations based on the broad subject material covered in medical school and postgraduate training would require considerable preparation on the part of most practicing physicians who have been away from the formal medical education environment for some years. While passing the examination is an indication of a physician's knowledge of appropriate medical information, it does not necessarily give an indication of the extent to which he applies this knowledge in his day-to-day practice situation, regardless of his ability to do so.

"An additional concern is that recertification and relicensure could become punitive if they became mandatory and were requirements of various government health care programs. Recertification and relicensure should be positive and practical in nature, not academic and punitive."

Guidelines on recertification for specialty boards were developed by the American Board of Medical Specialties and later revised in March, 1978. The present guidelines were published in the May-June 1978 issue of the CME Newsletter on page 4 and may be found there for review by interested readers.

It is not the purpose of my assignment to review arguments pro and con regarding recertification and relicensure, or to review once again the arguments for mandatory versus voluntary requirements, or to discuss the varied forces which are pressuring toward recertification as opposed to those forces in opposition, but to present factually the trends in recertification in relation to relicensure.

Twenty-three states now have legislation requiring

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JACKSON W. RIDDLE, M.D., Ph.D., Director, Div. of Educational Policy and Development, American Medical Association; Continuing Medical Education Newsletter, Nov. 1978, Vol. VII, No. 12.

some form of continuing medical education as a basis for reregistration of the license to practice, but not all of that legislation has been implemented to date.

Although the Federation of State Medical Boards of the United States has repeatedly urged the acceptance of recertification for reregistration of licenses, only the following nine states will give credit for recertification as a basis for reregistration of a license to practice: Arizona, Colorado, Massachusetts, Minnesota, Michigan (grants partial credit), Maryland, New Hampshire, New Mexico, Utah and Washington. Alaska and Ohio probably will give credit, but the issue has not yet been decided.

Let me give you a few examples of how individual specialty boards are facing the problems of recertification and the requirements which they are planning for recertification of their diplomates. These were discussed briefly on September 20, 1978 at the ABMS Conference on Recertification.

The American Board of Family Practice requires documentation of continuing medical education of 300 hours over a six-year period, unrestricted licensure, the passing of a cognitive examination composed of 175 multiple choice questions and a review of office records.

The American Board of Obstetrics and Gynecology recertification plans are based on practice profiles which describe 75 percent of the physician's activities. The cognitive examination is scored depending on the physician's practice profile, and an onsight review of practice is planned to replace the hospital practice profile and audit. Recertification will occur at a five-to-seven-year interval.

The American Board of Pathology plans to require as its evaluative process a choice among the following three alternatives:

(1) A cognitive written and practical examination, or

(2) 250 documented acceptable hours of continuing medical education, of which 120 must be Category 1, with 60 hours in the last three years prior to recertification, or

(3) Peer review through documentation of participation in quality assurance survey testing programs; plus an evaluation of an approved laboratory with continuing surveillance of laboratory activities; plus a specified number of continuing medical education hours.

The American Board of Surgery specifies that a candidate for recertification must have:

(1) 120 hours of acceptable Category 1 credit continuing medical education in the three years prior to a heavily clinically oriented examination with many patient management problems;

### REQUIREMENTS FOR SPECIALTY BOARD RECERTIFICATION**

The Specialty Boards have agreed in principle to require periodic recertification. The following are requirements for recertification. Other Specialty Boards will be adopting rules for recertification in the future.

| *Specialty Board* | *Challenge Examinations* | *Practice Audit* | *Continuing Medical Education* | *Self Assessment Test/Syllabus* | *Recertification Period* |
|---|---|---|---|---|---|
| American Board of Gynecology | X | X | | | 5-7 years |
| *American Board of Pediatrics | X | | Up to 80 hours of AAP sponsored CME or other CME | Optional | 6 years |
| *American Board of Allergy and Immunology | X | | X<br>(Amount of CME not set as yet) | Optional | 6 years |
| American Board of Plastic and Reconstructive Surgery | X | | 150 hours in past 3 years. ASPRS Program; PRA, and state, regional or professional society program with documentation of 50 hours CME in plastic surgery. | Optional | 6-10 years |
| American Board of Surgery | X | (Evaluation of Chief of Surgery or other official; and practice profile report) | 120 hours in past 3 years in surgical CME, at least 60 hours in Category 1 | SESAP can be reported for 60 hours CME | 7-10 years |

* Voluntary program; that is, original certificate stays in force if recertification not undertaken.
** Compiled by Arthur Osteen from data supplied by the American Board of Medical Specialties.

(2) A practice profile covering two years prior to application;

(3) Peer review and evaluation of practice privileges.

Efforts to evaluate technical skills are underway. Recertification will be carried out on a seven-year cycle.

In 1969, the American Board of Internal Medicine began a discussion among its members regarding the advisability of recertification. It accepted the concept one year later, and in October of 1974, became the first specialty board to offer a recertification examination. In the 1977 ABIM recertification examination, candidates participated in the first approach to the concept of some self-selection of patient management problems based on the individuality of their practices, as well as being tested for cognitive knowledge.

The American Board of Allergy and Immunology gave its first recertification examination in 1977. In its second Recertification Conference in 1978, this Board developed the following recommendations regarding recertification with the following requirements:

(1) Sufficient AMA Category 1 credits in two types of continuing education activities;

(2) Participation in the self-assessment program before taking the recertification examination;

(3) Passing a cognitive recertification examination prepared by the Board and based in a large part on the preceding self-assessment program similar in content and format to the Board's 1977 recertification examination.

The American Board of Pediatrics will grant recertification on the basis of elective credits and required credits in self education, through supervised cognitive examinations (two in a six-year period) and through self-assessment graded examinations (four in a six-year period). The first year's supervised examination is to be offered in 1980 in open-book format, in acknowledgment of the fact that such a testing format more closely resembles actual medical practice than total reliance on pure recall for answering questions about patients and their conditions. 80 credits of continuing medical education are also required.

The American Board of Thoracic Surgery has evolved a tripartite plan for recertification of candidates which consists of:

(1) Participation for credit in continuing medical education programs in the minimum of 50 hours per year of Category 1 programs for the two years prior to applying for recertification;

(2) Submittance of a practice review which would consist of a list of all major cases operated upon, including mortality statistics, during the previous two years, or 100 consecutive cases (whichever number is smaller) as a requisite to being declared eligible for recertification. Such a review would provide the Board with a practice profile for each candidate.

(3) Successful completion of a recertification examination to be given by the Board.

A syllabus in Thoracic Surgery is being developed which will be used as a preparation for the recertification examination. The syllabus will be ready for distribution in 1979 and the first voluntary recertification examination is planned for 1981.

The American Board of Anesthesiology will recertify candidates on a seven-year cycle starting in 1984. Components of the process will include continuing medical education requirements which will result in obtaining the Physician's Recognition Award of the AMA, and the passing of an examination which will accent knowledge important to the practice of all anesthesiologists, and which will also take the physician's practice profile into consideration. This Board is also still developing methods which will allow the:

(1) Evaluation of the recertification process;

(2) Evaluation of anesthesia skills or performance; and

(3) Alternative approaches to recertification, such as full-time participation in an approved training program for a brief period.

At the ABMS Conference on Recertification, there was no expression of opposition to this process. Either the attendees and speakers were carefully selected to present one point of view, or those attending the Conference realized that the train had already left the station and was now puffing merrily along the rails, gathering increasing momentum, and unable to be turned back. However, there is evidence of strong resistance in some of the boards toward recertification, for example, in the American Board of Dermatology. Also there is some concern that this form of examination may lead eventually to defined or specialty licensure.

Although I have been reporting to you regarding developments for the recertification of the diplomates of the specialty boards, I should briefly acquaint you with the developments for non-board certified physicians, of whom there are currently about 134,000.

In response to a resolution adopted by the Board of Directors of the Federation of State Medical Boards in 1976, at its first meeting in February, 1977, the National Board's Advisory Committee on Continuing Physician Evaluation began to study the need for evaluating the continuing competence of practicing physicians. Based on its continuing deliberations, in the view of the Committee, this evaluation may include a cognitive examination which reflects patterns of physician practice. As a basis for reregistration of the license to practice, this examination would be designed to evaluate physicians who are not certified by one of the recognized specialty boards, because specialty board recertification is gaining increasing acceptance.

Only if there is a serious expression of interest for such an evaluation process on the part of the Federation of State Medical Boards or by one of its medical licensing jurisdictions, would the National Board of Medical Examiners be involved in preparation of an examination. The examination would be used only as part of a process leading to the reregistration of an existing license to practice, and would be administered only by or on the authorization of one of the state medical boards for the Federation of State Medical Boards.

The reports of individual performance evaluation on such an examination would be submitted only to the licensing agency. The report would indicate only that the candidate had or had not met the standards accepted by the licensing authority. The report would state specifically that the process was not equivalent to certification or recertification by a specialty board, and no certificate would be issued to individual physicians. Such an examination should address those areas of competence requisite for all physicians, and in addition, should reflect the knowledge and skills related to the individual physician's practice pattern.

In summary, it is apparent that specialty board recertification is a reality, and rapidly being implemented. Although only nine licensing jurisdictions to date have accepted recertification as a basis for licensure reregistration, other states can be expected to follow. Most boards are preparing syllabi, study manuals or specific courses for use by candidates for recertification.

Of those specialty boards which to date have refined their criteria for recertification, the majority have indicated three primary requirements:

(1) A cognitive examination related to the physician's practice profile;

(2) Some form of evaluation of his competence through record reviews, practice audits, etc.; and

(3) Documented participation in continuing medical education, along lines similar if not identical to those required for the AMA's Physician's Recognition Award.

It is this last requirement that addresses the heart of the issues of this Conference, and it is, therefore, why we are asking your help in making CME credit hours for the PRA more meaningful.

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## Informed Consent Regulation

The regulation of the State Department of Health Services on informed consent provides that hospital medical staff bylaws require the responsible physician, except in emergency situations, to obtain proper informed consent prior to any procedure or treatment for which it is appropriate, and to document such consent either by a form signed by the patient, or by a statement on the patient's *hospital* record signed by the physician.

Since lack of informed consent is a common allegation in malpractice complaints, the importance of adequate documentation of the informed consent conversation between physician and patient cannot be overstated with respect to the successful defense of physicians. Such documentation is essential for such procedures or treatments whether performed in the office or the hospital, but a note in the *office* record does not suffice for procedures carried out in the hospital setting, in complying with the language of the new regulation.

# Month in Washington

The President's sacking of Health, Education and Welfare Department Secretary Joseph Califano has generated speculation on "why" to the measure of tons of national newsprint. But after a terse *ave atque vale* to the deposed Secretary, more prosaic Washington observors have quickly turned to handicapping his successor, Patricia Roberts Harris.

The 55-year-old Harris, a lawyer, brings to HEW much of the same Lyndon Johnson "fair deal" outlook as Califano. She is regarded as more of a team player, but her prickly independence is reminiscent of her predecessor. She can be expected to enthusiastically support the Administration's goals at HEW, including the establishment of a separate Department of Education, a reorganization that Califano not so privately opposed to the discomfiture of the White House.

Harris hasn't been rated as one of the heavyweights of the Cabinet, perhaps because her Department ranks last in importance. Now she has her chance. Long active in the Democratic Party, she served two years as Ambassador to Luxembourg in 1965-67 and was later an alternate delegate to the United Nations. She was an attorney with the Justice Department in the early 1960's, and later became a successful private lawyer in a Washington, D.C. law firm. She has been a director of some of the nation's largest corporations.

In the press brochure distributed at her news conference following announcement of her appointment to HEW, copies of news stories about Harris were included. They carried such headlines as "Forceful HUD Secretary is turning her critics around; Patricia Harris, HUD's Velvet-gloved Iron Hand; HUD Secretary Harris Steps Quickly Into The Fray; and Patricia Harris-The No-Nonsense Chief of HUD."

"Abrasive," "Pugnacious," "Spitfire" were some of the adjectives used in the articles to describe Harris; apparently descriptions with which she is comfortable.

As a "Team Player" Harris said nothing remotely controversial at the news conference. She has filled out and returned an inane White House questionnaire sent to all Cabinet members asking them to rate their subordinates on a variety of qualities. Califano had refused to honor the questionnaire.

But there is still a lot of head-scratching in Washington. The Administration's two major health initiatives—hospital cost containment and the national health plan—are widely and strongly identified in the Congress with Califano. Harris has no expertise in health and no strong clout with the small but powerful "Old Boy" Democrat band of brothers in the Congress. And it will take her months to learn the ropes.

* * * *

An amended version of the Administration's Hospital Cost Containment Bill (H.R. 2626) has cleared the House Ways and Means Committee. In the Senate, the Finance Committee earlier rejected a modified version of the Administration measure offered by Sen. Gaylord Nelson (D-WI).

First, the Senate Finance Committee stemmed the Administration by rejecting the proposal 11-9. Six days later Ways and Means kept the plan alive with a 22-14 approval of an amendment-laden measure.

There's no chance of floor action in either Chamber before September. The high priority Presidential plan to impose federal controls on hospital revenue increases if they top a certain level was approved by the Senate last year, but the bill failed to reach the House floor.

Despite the Finance Committee vote, an attempt will be made to bring the bill up in the Senate. The outlook in House and Senate is for very close votes.

The vote in Ways and Means, 22-14, wasn't a true test of Committee sentiment on the measure. For two months Committee Chairman Al Ullman (D-OR), was unable to bring the bill before the Committee for action because a majority of the panel was opposed to the bill. Phone calls from President Carter switched one or two Democratic votes. The plea was to allow the full House to vote on the issue.

A 20 to 16 vote approving an "open rule" for proposal was regarded as more indicative of Committee feelings. The "open rule" allows unrestricted amendments on the floor of the House that could weaken a bill and is not sought usually by backers of legislation.

The Senate Finance Committee's turn-down of the plan was a shock to the White House which thought it had sewed up the powerful Committee with the commitment from Chairman Russel Long (D-LA), a previous foe of the plan, to support it. Long did cast his vote with the Administration, but it wasn't enough to win the day. And it was apparent he had twisted no arms to see it his way.

The successful fight against the Administration plan, offered by Sen. Nelson, was led by Sen. Robert Dole (R-KANS), top GOP member of the Committee.

Dole suggested that if Congress adopted the hospital bill some future President might have to go

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*Prepared by the Washington, D.C.*
*Office of the American Medical Association*

the "mountain top" a la President Carter and try "to figure out what happened when we adopted the Nelson Price Control Amendment to hospital care and we started rationing health care in this country."

"Government obviously is not the best manager in the world," Dole said, "yet in this bill it attempts to reach out and manage 6,000 hospitals in this country."

On the key vote, all eight Committee Republicans plus Sens. Talmadge, Lloyd Bentsen (D-TX), and Mike Gravel (D-ALAS) voted no.

Before voting on final passage, the House Ways and Means Committee spent several days approving a series of amendments softening the impact of the bill. A Committee member complained that, as a result, 65 percent of the nation's hospitals wouldn't be covered. Among other amendments adopted were a lifting of the ceiling on revenue increases to 11.6 percent a year; a requirement that Congress be given notice by HEW of a move to trigger controls and an opportunity to block them; inclusion of all federal hospitals—including Veterans' Administration facilities—in the control plan; exclusion of philanthropic contributions to hospitals in tabulating revenue; and exclusion of the costs of providing charitable care.

The Bill also exempts or gives special consideration to many types of health facilities—certain tertiary care centers, children's hospitals that give charity care, Shriners' hospitals, hospitals with lower than average lengths of stay, and Alaskan and Hawaiian hospitals—due to increasing populations and the high costs of living.

The major "pass through" in the plan, part of the bill from the beginning, is the exclusion of wage increases for nonsupervisory hospital personnel. This was necessary to secure labor's support.

The Administration's original proposal last year provided immediate imposition of controls, but it was forced to accept a standby plan triggering controls only if the Voluntary Effort failed to bring increases down to a certain level.

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Interns, residents and other housestaff who choose to organize formally should be able to avail themselves of the rights established for employees by the National Labor Relations Act, the American Medical Association has told the Congress.

Approval was urged of legislation granting housestaff this right by William Mangold, Jr., M.D., Vice Chairman of the AMA's Council on Legislation. He said that to argue housestaff are only "students" is to ignore the inherent duality of graduate medical education.

"Generally, an individual having the status of an employee is subject to supervision," said Dr. Mangold. "Employees receive compensation for their services, and their services are expected to have value to their employers. Employers are required to withhold federal and state income taxes and to pay Social Security taxes in connection with wages or salaries paid to employees. Each of the foregoing applies to the relationship that exists between employing institutions and interns and residents."

He told a House Labor Subcommittee that compensation is provided by hospitals to housestaff just as other employers pay for value received. "The motivation on the part of the hospital is not just to subsidize graduate medical education but to pay for services."

Recognition of the importance of the educational component does not detract from the residents' status as employees, Dr. Mangold said, "but only acknowledges the dual role of the physician during the period of internship and residency."

This duality should not detract from the physician's rights when he or she is employed, he added. "Among these rights is the freedom to organize and bargain collectively if the physician so chooses."

At the same time, the AMA witness said NLRB coverage for housestaff carries with it special responsibilities. "Collective bargaining and negotiations must be conducted judiciously and contained within proper limits by the respective parties. The exercise of mature judgment and experience, with special regard for the educational and patient care responsibilities of both employee and employer, will be necessary. If not, the result could be disruption of necessary patient care and interference with the quality of graduate medical education. The pursuit of legitimate objectives should not dilute the quality of patient care or graduate medical education."

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The Senate Finance Committee has voted to bar recognition of Medicare-Medicaid percentage arrangements for hospital based specialists. The provision, part of an overall Medicare-Medicaid measure, would generally become effective on October 1, 1979.

Percentage arrangements entered into by hospitals and physicians before January 1, 1979, could be recognized for Medicare-Medicaid reimbursement purposes until January 1, 1982, or the earliest date they could be terminated by the hospital, whichever is earlier.

The Committee suggested that HEW give serious consideration to providing that full fees be paid to an anesthesiologist only where he personally performs all the professionally appropriate pre-and-post-anesthetic services and carries out the most demanding procedures in connection with administration of the anesthesia for no more than two patients. Provision is made for lesser payments where the anesthesiologist directs or supervises nurse anesthetists.

# The President's Page

## I'll Take an "Eagle Scout" Everytime

The "Truth in Testing Bill" recently signed into law in New York has added to the problems faced by medical school admissions committees. Because it provides for disclosure of the correct answers to the examination questions, the frequency of test changes will have to be increased and the time interval devoted to the development of valid questions will have to be diminished. Thus, a test already subjected to criticism by some as a valid prognosticator of success in medical school performance may perhaps become less reliable.

Medical school admissions committees need some independent method of evaluating applicants besides grade scores achieved as undergraduates. Candidates apply from numerous colleges with different grading standards throughout the country; therefore, as an objective method of evaluation the MCATs serve a purpose offering some balance in the overall selection of applicants. Too often, however, these tests provide an easy out for some medical school admissions committees. It was sometimes more convenient and expedient to rely on the quantitative evaluations rather than emphasize subjective judgement which a committee might be called upon to justify at some later date.

Regrettably, the combination of grade scores and test scores began to carry so much weight in the decision-making process by the schools that competition for scores by applicants soon began to supersede the students' other accomplishments in their selection for admission to medical school.

Oftentimes students with high academic grades and understanding, empathetic temperament but with substandard MCAT scores were looked upon by admissions committees as overachievers who might be less desirable as medical school candidates. (Poor Albert Einstein might never have made it.)

The overwhelming number of those chosen on the basis of grades and MCATs, were felt to have achieved the perfect combination of qualifications and therefore, except for specific exceptions in the direction of social engineering only the most brilliant were selected.

Unfortunately, however, also among those selected by these standards were some of the most competitive, aggressive, materialistic, and callous candidates that our colleges could produce.

All of this has been going on with very little input from the large community of practicing physicians and with almost no input from the general public, whose sensitivity to patient needs is often overlooked.

Certainly a keen mind, as evidenced by academic achievement, is needed to absorb and astutely apply the rapidly changing store of medical knowledge, but equally important, to my way of thinking, is the presence of those human qualities such as patience, compassion, understanding and empathy. Surely devotion to the needs of others, responsibility to duty and achievement through sacrifice and dedication are equally as important as MCAT's.

If perchance "the truth in testing" bill leads to the demise of the MCATs it might be regretable. One would then have to fall back on clinical judgement and if I had to choose a medical student from amongst those with similar qualifications I would select an "Eagle Scout" everytime, secure in the knowledge that my judgement would most likely be vindicated.

It would be most helpful, however, if the Boy Scouts and the Girl Scouts would provide us with an equal list from which to select.

Edward A. Kamens, M.D.
*President*

# Reflections from the Dean's Office

## Limits to Growth

ROBERT U. MASSEY, M.D.

In his recent book *American Medicine: Challenge for the 1980's,* David Rogers writes:

> "And what of the size and complexity of our academic centers? Here I would suggest 'imaginative retrenchment.' I have written elsewhere that academic medical centers must recognize that they probably now capture about all the financial resources this country can afford and that they must begin to prepare for a steady state in which they still can become better, but probably not bigger."[1]

Between the academic year just passed and the year beginning this month, tuition costs have risen 13 percent in public medical schools and 11 percent in private medical schools, and student fees have risen over 50 percent. Including board and room, the cost of attending a private medical school in 1979-80 will average $10,500; for state residents attending their public medical school, the average cost will be about half that. Tuition costs alone at some private medical schools are now as high as $13,500. In Connecticut, tuition, fees, and room and board will total at least $7,000 for residents, and $8,400 for non-residents.[2]

Next year the average indebtedness for University of Connecticut medical students at graduation will be $15,000, with some loans carrying a 12 percent interest rate. In some private schools student debt may be three or four times this amount.

In 1976 the nation's 120 academic medical center budgets totaled 12.5 billion dollars, or an average of about $96,000,000 for each center. This includes the university teaching hospital in each instance, as well as the other health professional schools associated with the center. For the University of Connecticut Health Center, which includes the School of Medicine, the School of Dental Medicine, and the John Dempsey Hospital, the budget this year will be $76,000,000, of which 31 percent will come from State appropriations.

The Combined budgets of 111 medical schools in 1976-77, was $3,901,000,000. This is an increase of 232 percent in medical school costs for the nation in nine years. On average, budgets were up 166 percent, or 14.3 percent per year, representing a real annual growth rate of 7.3 percent compounded.[3]

The American Medical Association Annual Report on Medical Education for 1977-78 shows that federal research support, which accounted for 29.5 percent of total budgets in 1967-68 for public medical schools, accounted for only 15.8 percent in 1976-77. Professional fees, on the other hand, accounted for 5 percent of the revenues in public schools in 1967-68, and 3.3 percent for revenues in private schools, but in 1976-77 had risen to 10.7 percent and 12 percent respectively. Meanwhile state support for public schools had increased from 26.2 percent to 35.5 percent.

These trends support David Rogers' counsel of "imaginative retrenchment". Federal enthusiasm has diminished and legislators are talking about a doctor glut. Students cannot bear a much larger burden of expense and debt. Faculty members cannot devote much more of their effort to clinical work without impairing their research and short-changing the students. State legislators are faced with tax resistance, and a decline in tax revenues. With inflation over 10 percent and recession now certain, the medical schools' annual real growth rate of 7.3 percent may not continue.

In the 35 years since World War II, we have seen biological knowledge and medical technology grow faster than ever before. The output of physicians has doubled, the doctor shortage predicted in 1958 has not occurred, and most of our indices of health have improved. The death rate has fallen 14 percent in the past eight years, perhaps not entirely the result of more and better medical care, but certainly not unrelated.

During this time of "imaginative retrenchment", scientific growth must not stop, for it is not easily started up again, and quality must not decline, because that can go unnoticed until it is too late. We need to continue to face up to unresolved issues, those that remain either because of our ignorance, or because we are too badly organized to handle them. We shall need to be selective in our retrenchment so that essential things can grow or improve as rapidly as ever, and other achievements will not be lost.

Cost containment is not only a matter for hospitals and practicing physicians. Medical education and biomedical research are also up against the fact of the marketplace. Just as we have an obligation not to let the quality or care slip, even if Mr. Carter's cost containment legislation passes, so we have an obligation to sustain the quality of medical education and the *growth* of biomedical science.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

# Abortion 1979: The Concept of Viability

JOSEPH M. HEALEY, J.D.

The decisions of the United States Supreme Court in the 1973 cases of *Roe v. Wade*[1] and *Doe v. Bolton*[2] did not resolve the complex legal, moral and medical issues surrounding abortion, but rather provided a new framework for the continuation of the societal debate. In those decisions, the Court held that the constitutional right of privacy was broad enough to encompass the decision of a woman to terminate a pregnancy by abortion. This right, though fundamental, was not absolute and was subject to restriction in the name of two important state interests: protection of the health of the woman and protection of the actual or potential life of the fetus. Each of these interests could become compelling at a stage of the pregnancy. For protection of the health of the woman, that stage was the beginning of the second trimester. For protection of the actual or potential life of the fetus, that stage was the existence of viability. States could, if they chose, regulate the abortion decision subsequent to these critical points, to further either or both interests. However, a woman may not be denied abortion when it is deemed necessary, according to appropriate medical judgment, to preserve the life or health of the pregnant woman.

The concept of viability is central to this legal framework, In the recent case of *Colautti v. Franklin*,[3] the Supreme Court was asked to review a Pennsylvania statute which dealt with this concept. The decision of the Court provides guidelines for physicians who must make the difficult judgment whether a fetus is viable or non-viable.

The Pennsylvania Abortion Control Act required those who were performing abortions to determine beforehand that the fetus was not viable. If the physician determined that the fetus was viable or if there was sufficient reason to believe that the fetus might be viable, the physician would be obliged to exercise care to preserve the life and health of the fetus. Such steps would include using the abortion technique most likely to allow the fetus to be aborted alive, so long as a different technique would not be necessary to preserve the life or health of the mother. A lawsuit was filed alleging that several of the provisions of the Act were unconstitutional. The trial court upheld some of the provisions and rejected others. As a result, both sides appealed to the United States Supreme Court. In a 6-3 decision, the Court held that the provision requiring a physician to determine whether a fetus is or may be viable before performing an abortion was unconstitutionally vague because it failed to specifically define standards for making such determinations. The vagueness of the statute and the absence of a scienter requirement (that the physician acted knowingly) subjected physicians to potential criminal liability without regard to fault. Furthermore, the requirement that the physician who has determined that the fetus is viable or may be viable use medical techniques offering the best chance of fetal survival was also impermissibly vague. Therefore, these sections of the Act were declared unconstitutional in violation of the Fourteenth Amendment.

Mr. Justice Blackmun, writing for the majority, reviewed earlier formulation of the concept of viability and pointed out that under the formulations in those cases, a fetus would be considered viable if it had the capacity for meaningful existence independent of the mother's womb, albeit with artificial aid. In one case, *Planned Parenthood v. Danforth*,[4] the Court had stated its position that it was not the function of the legislature or the courts to place viability, essentially a medical concept, at a specific point in the gestation period. Because the time when viability is achieved may vary with each pregnancy, the Court considered the determination of whether a particular fetus was viable to be a matter of judgment for the physician. Blackmun, reviewing these prior decisions, set forth the current status of the concept of viability:

> In these three cases, then, this Court has stressed viability, has declared its determination to be a matter for medical judgment, and has recognized that differing legal consequences ensue upon the near and far sides of that point in the human gestation period. We reaffirm these principles. Viability is reached when, in the judgment of the attending physician on the particular facts of the case before him, there is a reasonable likelihood of the fetus' sustained survival outside the womb, with or without artificial support. Because this point may differ with each pregnancy, neither the legislature nor the courts may proclaim one of the elements entering into the ascertainment of viability— be it weeks of gestation or fetal weight or any other single factor— as the determinant of when the State has a compelling interest in the life or health of the fetus. Viability is the critical point. And we have recognized no attempt to stretch the point of viability one way or the other.

Next month, we will continue a discussion of recent Supreme Court decisions, focussing on the rights of minors in the health care process.

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# Editorials

## The AMA Meeting—July 1979

Of all the many medical meetings I have ever attended, I am most enthusiastic and impressed by the AMA meetings. The recent annual meeting in July was no exception. In a 5-day meeting, the House of Delegates considered 262 resolutions and reports, besides its annual time-consuming election of officers.

From a study of voluntary (nongovernmental) national organizations, I have stated that the AMA is the most democratic in organization and practice. Though this is received with skepticism, especially by those who know little about the AMA, many of whom are physicians, it has never been successfully rebutted.

The AMA used to be criticized for being too conservative and reactionary, especially in our area. Lately, however, many physicians, especially in other parts of the country, criticize it for being too liberal. In these last few years, it has moved more to center, quite like the people of our country and Congress.

Increasingly its House of Delegates is being influenced by important changes in its make-up, namely the increasing membership and influence of the students and residents. The House has leaned over backwards to include them, and they have proved to be responsible with a recognizable impact on the House and in important committees. Recently delegates from the Section of Medical Deans, and from each of the 50 or so national specialty societies, more of which are applying for representation in the AMA, contribute toward making the AMA the umbrella organization for the profession in our country in social, political, legislative, economic and ethical issues, still with a strong impact on medical education at all levels.

Nonmembers at least know that the government in one form or another is intruding into medical affairs, medical education, research, and even ethics. We in Connecticut should particularly appreciate legal intrusion and its cost with the present FTC suit against the AMA, CSMS, and the New Haven County. All three will appeal the present adverse decision of the solitary FTC judge to the Supreme Court if necessary. This costs money. The AMA presently is spending about $100,000 a month in legal expenses. The AMA is also defending itself against suits brought by chiropractors in various states on the grounds of conspiring to limit their practices in violation of the Sherman Antitrust Act. Recently, the New York state's attorney has brought suit against the New York State Medical Society on the same grounds, compounding the problem by writing to all other states' attorneys suggesting that they do the same thing. Everyone in the practice of medicine in our state realizes how much the law has intruded into our practice and into our relation with our patients, not only malpractice, but notably the recent State regulation on consent that has all the force of law. It should be obvious that we all need to share in financially supporting the AMA in its efforts to preserve our profession.

There were four issues in the meeting that were especially important: (1) medical ethics, (2) national health insurance, (3) continuing medical education, and (4) chiropractic.

*The Principles of Medical Ethics.* At the June, 1978, meeting, the Judicial Council presented a complete revision of the Principles on recommendation of the legal department. They contain provisions that have made, and would make, the AMA liable to litigation especially by the Federal Trade Commission. These relate especially to chiropractic, price competition, advertising and solicitation, issues that could be considered illegal according to the Sherman Antitrust Act. The House rejected the revision and referred the problem to an ad hoc committee of the House, which reported at this session. After prolonged study and consultation with both legal and ethical experts during the year, the committee presented an entirely new version. The House again rejected adoption, and voted to have it sent to all county, state and specialty organizations for comments and recommendations. This committee will present a version, with alternatives, to the House at its next session.

In spite of numerous suits now pending and legal advice, some delegates, organizations and members oppose any changes in the code. But the majority, while satisfied with the present Principles, have been persuaded that the legal hazards are compelling.

*National Health Insurance.* For some years the House, acting on recommendation of the Board of Trustees, has adopted the principle that the AMA should have its own comprehensive health insurance plan to present to Congress as a positive approach to the problem and also to have it as a negotiating instrument in the political process in Congress. At our last session, however, when the Board introduced an up-to-date plan, the Florida delegation introduced a resolution that was adopted by a sizable majority. In effect, it held that the climate of opinion in the public and in Congress no longer supported a universal comprehensive health plan. In brief, its four principles were adopted; they provided for minimum benefit standards in health insurance policies, uniform government benefits for those unable to afford coverage, nationwide catastrophic insurance covered by the private insurance industry, and administered by the states with national standardization through federal guidelines.

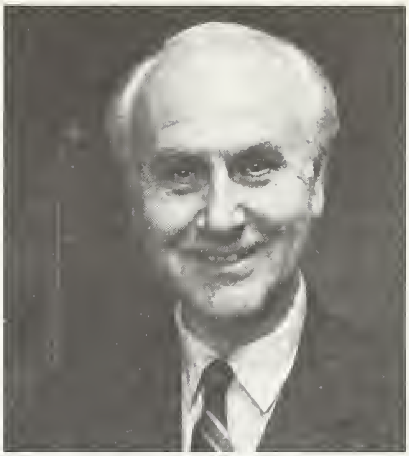
The House reaffirmed the Florida principles. But it gave the Board authority to be flexible, and to draft a comprehensive health insurance bill only if necessary. This action by the House of course is a definite important change in philosophy by the AMA.

*Continuing Medical Education.* This was important because the House voted to withdraw from the Liaison Committee on Continuing Medical Education (LCCME). Made up of the Association of American Medical Colleges, American Board of Medical Specialties, Council of Medical Specialty Societies, American Hospital Association, Association for Hospital Medication, Federation of State Medical Boards, and the AMA, with public and federal government representatives, it has for the past few years been the accreditor of CME in the profession. The AMA pays for 90% of its budget and donates secretarial services. Its greatest responsibility is CME for practicing physicians. Increasingly, however, over the objection by the AMA member, it has taken more and more authority over CME, at the expense of state societies and the AMA. Our delegate and the Council on Medical Education of the AMA have tried to stop this trend and to effect compromise, but in vain. They reported to the House that they were unable to inject even a minimal input into the LCCME. The House accepted the recommendation of its delegate, immediate past president Tom E. Nesbitt and of the Council on Medical Education to withdraw completely and immediately. The AMA will now be the primary accreditor of CME, recognizing state medical associations as the accrediting bodies for institutions and organizations providing local CME programs at the local level.

*Chiropractic.* Several potentially serious suits are now pending against the AMA involving chiropractors. Their legal grounds are based on decisions of the Supreme Court and actions of the FTC, namely that professions no longer are immune to provisions of the Sherman Antitrust Act. Also, our Principles of Medical Ethics and interpretations of the Judicial Council have classified chiropractic as quackery and a cult. The code also states that physicians should not associate with unscientific practitioners. This has been responsible for the need to revise our code. Essentially the legal grounds for their suits are alleged violation of the Sherman Antitrust Act and provisions of the FTC Act. The suits roughly allege restraint of trade, of competition, price fixing by fee schedules, elimination of price competition, by prohibition against advertising and solicitation, and legally unfair competition against other health professions, especially chiropractors.

Proposed changes in the Principles and chiropractic have been major issues during the last three sessions without definitive action or resolution. They are on the agenda for the next session also. They are serious and reflect the changing conditions and relations of physicians to other professions and the use of litigation to resolve such disputes. Each reference committee of the House has a lawyer from the Staff to advise it; each resolution and recommendation to the House is carefully scrutinized by our legal department; each final action of the House is also scrutinized by our legal department, sometimes advising the House through our Exective Vice President. It is serious, frustrating, but a fact of life. I hope that our state nonmembers of the AMA will try to emulate the students and residents in their support of the AMA not only by greatly increased membership, but also by their financial support.

Fred Fabro, M.D.



# Orvan W. Hess, M.D., Receives AMA Scientific Achievement Award

Dr. Orvan W. Hess, Clinical Professor of Obstetrics and Gynecology at Yale University School of Medicine and Director of the Perinatal Monitoring Program at Yale-New Haven Hospital, has received the very prestigious Scientific Achievement Award from the American Medical Association in honor of his contributions to clinical research, including the development of techniques and equipment to accurately monitor the fetal heartbeat. He began his work in this area around 1937 when he was still a Resident. In 1957, for the first time, it became possible to isolate the fetal heart rate from the mother's during labor and determine whether changes in rate and rhythm were related to uterine contractions or abdominal obstetrical conditions. Doctor Hess has continued his research in this area and during the 1960s devised a system of telemetering the fetal electrocardiogram and intrauterine pressure during pregnancy and labor. Thus it is possible to keep a continuous, accurate check on the unborn baby's heartbeat even when medical personnel are unable to be in the same room. The electrical signals are monitored and transmitted by short-wave radio. Further refinements include reducing the equipment in weight and size making it easier to use and more adaptable during many types of operations on pregnant women, and using ultrasound to monitor the fetal heart activity continuously from the external abdominal wall of the mother. Dr. Hess also pioneered in studies of wound-healing of the uterus after Cesarean Section. The results of his work have been widely published and he has lectured on the subject throughout the United States and numerous countries around the world. The Award is made in recognition of outstanding work in applied medical research and is presented on a selective basis by decision of the AMA Board of Trustees. Dr. Hess received the Award in ceremonies held during the 128th Annual Meeting of the AMA House of Delegates in Chicago, Illinois on July 22nd.

In addition to his clinical work, he has been extremely active in many hospital and medical affairs, is a past president of the Connecticut State Medical Society and was Director of Health Services of the Connecticut Welfare Department during the inception of Medicare and Medicaid. Dr. Hess is currently a Delegate to the American Medical Association.

*Dr. Robert B. Hunter, Chairman AMA, Board of Trustees, presenting the 1979 Scientific Achievement Award to Dr. Orvan W. Hess before the House of Delegates 128th AMA Meeting on July 22nd. Dr. Hunter is the new President-elect of the A.M.A.*

# Medical and Health News

PHYSICIANS' FEES ROSE AT A RATE OF 0.5% in June, less than half as much as the all items and all services categories of the government's Consumer Price Index. The all items component of the index increased 1.2% and the all services component rose 1.1%. June was the fifth consecutive month in which the overall cost of living galloped far ahead of physicians' fees.

The CPI figures were released as the AMA House of Delegates adopted a Board of Trustees report calling for reaffirmation of the AMA's commitment to a program of voluntary restraint of physicians' fees. "Although physicians' fees have shown restraint relative to the rest of the economy," the report said, "the rate of fee escalation is still substantial. Given the current inflationary pressures, increased efforts by the AMA will be required to actually reduce the rate of fee escalation."

The AMA program, adopted by the House last December, is in response to the presidential inaugural address of Tom E. Nesbitt, M.D., at the 1978 Annual Convention. He asked physicians to moderate the rate of their fee increase by 1% in each of the next two years. In May the AMA distributed a booklet, "Physician Fee and Cost Indicators," which provides a step-by-step method to help individual physicians manage their practices more efficiently and restrain fee increases. These booklets are available from AMA Order Dept., P.O. Box 821, Monroe, Wis. 53566.

THE AMA WILL CONTINUE TO WARN THE PUBLIC of the hazards in entrusting the diagnosis and treatment of such diseases as essential hypertension, heart disease, stroke, cancer, diabetes and infections "to practitioners who rely upon the theory that all disease is caused by misalignment of spinal vertebrae and can be cured by manual manipulation and adjustment of the spine." A Board of Trustees report on chiropractic, asserting that the AMA knows of no scientific evidence to support spinal manipulation and adjustment as appropriate treatment for such ailments, was adopted by the House of Delegates at the Annual Meeting last month.

The report states that "it is better to call attention to the limitations of chiropractic in the treatment of particular ailments than to label chiropractic an 'unscientific cult,' " since not everything a chiropractor may do when acting within the scope of a license granted by a state is necessarily without therapeutic value.

The report reaffirms the AMA position that "a physician should at all times practice a method of healing founded on a scientific basis." It states that a physician may refer a patient to another physician, a licensed limited practitioner, or any other provider permitted by law to furnish health care services whenever the physician believes referral will benefit the patient. The report also states that the AMA "supports the right of every physician to choose those persons whom he or she will accept as patients and also to exercise his or her choice by the terms of contractual arrangements with other physicians, medical groups, hospitals or other institutions."

—*AMA Newsletter*, August 6, 1979

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**WARNINGS**: If tolerance develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Tenuate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly. *Drug Dependence*. Tenuate has some chemical and pharmacologic similarities to the amphetamines and other related stimulant drugs that have been extensively abused. There have been reports of subjects becoming psychologically dependent on diethylpropion. The possibility of abuse should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with varying degrees of psychologic dependence and social dysfunction which, in the case of certain drugs, may be severe. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. *Use in Pregnancy*: Although rat and human reproductive studies have not indicated adverse effects, the use of Tenuate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential risks. *Use in Children:* Tenuate is not recommended for use in children under 12 years of age.
**PRECAUTIONS**: Caution is to be exercised in prescribing Tenuate for patients with hypertension or with symptomatic cardiovascular disease, including arrhythmias. Tenuate should not be administered to patients with severe hypertension. Insulin requirements in diabetes mellitus may be altered in association with the use of Tenuate and the concomitant dietary regimen. Tenuate may decrease the hypotensive effect of guanethidine. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Reports suggest that Tenuate may increase convulsions in some epileptics. Therefore, epileptics receiving Tenuate should be carefully monitored. Titration of dose or discontinuance of Tenuate may be necessary.
**ADVERSE REACTIONS:** *Cardiovascular*: Palpitation, tachycardia, elevation of blood pressure, precordial pain, arrhythmia. One published report described T-wave changes in the ECG of a healthy young male after ingestion of diethylpropion hydrochloride. *Central Nervous System*: Overstimulation, nervousness, restlessness, dizziness, jitteriness, insomnia, anxiety, euphoria, depression, dysphoria, tremor, dyskinesia, mydriasis, drowsiness, malaise, headache; rarely psychotic episodes at recommended doses. In a few epileptics an increase in convulsive episodes has been reported. *Gastrointestinal*: Dryness of the mouth, unpleasant taste, nausea, vomiting, abdominal discomfort, diarrhea, constipation, other gastrointestinal disturbances. *Allergic*: Urticaria, rash, ecchymosis, erythema, *Endocrine*: impotence, changes in libido, gynecomastia, menstrual upset. *Hematopoietic System*: Bone marrow depression, agranulocytosis, leukopenia. *Miscellaneous*: A variety of miscellaneous adverse reactions has been reported by physicians. These include complaints such as dyspnea, hair loss, muscle pain, dysuria, increased sweating, and polyuria.
**DOSAGE AND ADMINISTRATION:** Tenuate (diethylpropion hydrochloride): One 25 mg. tablet three times daily, one hour before meals, and in midevening if desired to overcome night hunger. Tenuate Dospan (diethylpropion hydrochloride) controlled-release: One 75 mg. tablet daily, swallowed whole, in midmorning. Tenuate is not recommended for use in children under 12 years of age.
**OVERDOSAGE**: Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Overdose of pharmacologically similar compounds has resulted in fatal poisoning, usually terminating in convulsions and coma. Management of acute Tenuate intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendation in this regard. Intravenous phentolamine (Regitine®) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates Tenuate overdosage.

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## COUNCIL MEETING

Wednesday, August 8, 1979

### Attendance

Present were: Drs. Kamens, James, Canzonetti, Backhus, Mendillo, Sadowski, Freedman, Hess, Van Syckle, Fabro, Whalen, Jr., Cramer, Friedberg, McGarry, Anderson, Magram, Parrella, Barrett, Zlotsky, Beck, Abbot, Seide, Shenker, Eslami, Tierney and Bobruff.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Sweeney, Mr. Brunell and Mr. Fiorentino (FCMA).

### Review of Film

Prior to consideration of the agenda items, the Council viewed a film produced by the Aetna Insurance Company on the Connecticut Commission on Hospitals and Health Care.

### Report from Physicians Serving on State and Federal Agencies

Statewide Professional Standards Review Council—Dr. Isadore H. Friedberg mentioned that the Council had lost its executive director and that the organization was cosponsoring a program on the lack of availability of extended care facilities and skilled nursing beds primarily in Fairfield County but also throughout the state. It was also reported that three out of the four PSROs have new executive directors.

HSA—Dr. Mehdi S. Eslami mentioned that HSA #5 is currently involved in a self-assessment program. He also expressed concern because the HSA representation to SHCC is comprised of three consumers and one provider compared to the two consumers and two providers supplied by every other HSA. Dr. Eslami said that a protest has been filed.

SHCC—Dr. Edward A. Kamens reported that activities have been curtailed somewhat over the summer and that pressure has been applied on Washington for the continued funding of the SHCC and the HSAs.

### Appointments

(a) *Connecticut Statewide Professional Standards Review Council:* It was VOTED to designate Dr. Charles M. Krinsky as the CSMS representative on the Connecticut Statewide Professional Standards Review Council.

(b) *Committee on Allied Medical Services:* It was VOTED to add Drs. Paul S. Goldstein, Brian F. Rigney, and Donald S. Dock, all of New Haven, to the CSMS Committee on Allied Medical Services.

### Metropolitan Life Insurance Company Second Opinion Program

It was VOTED to appoint a committee of five physicians (appointed by the President and the Chairman of the Council) chaired by President Edward A. Kamens, to meet with Dr. Robert Henderson of the Metropolitan Life Insurance Company and establish guidelines for a possible second opinion program, followed by a report back to the Council. The Council agreed that any such program should guarantee the documentation and retrievability of data and that any release to the media of such data should first come before the Connecticut State Medical Society.

### Report from John Barrasso, M.D.

John Barrasso, M.D., a resident at Yale-New Haven Hospital and successful candidate for a position on the AMA Council on Constitution and Bylaws, appeared before the Council to thank the members for their support of his candidacy at the recent AMA Convention in Chicago and expressed a desire to work with the Society on matters related to his AMA Council work.

### AMA Annual Convention Chicago, Ill., July 22-26, 1979

Dr. Guy W. Van Syckle reported on the recently concluded AMA Convention in Chicago. He mentioned that the matter of revising the medical ethics was delayed for further review and that the AMA House of Delegates had voted to drop its membership in the Liaison Committee on Continuing Medical Education (LCCME).

Dr. Van Syckle also reported that AMA membership figures were down and that plans were being studied which might change the AMA from a federation to an organization of organizations. The AMA

House of Delegates reaffirmed the position taken in December, 1978, on national health insurance embodying the following four principles:

1. Requiring minimum standards of adequate benefits in all health insurance policies sold in the United States with appropriate deductible and co-insurance.
2. A simple system of uniform benefits provided by the federal, state and local governments for those individuals who are unfortunate (through no fault of their own, i.e., age, disability, financial hardship, etc.) not to be able to provide for their own medical care.
3. A nationwide program by the private insurance industry of America (and government if necessary for reinsurance) to make available catastrophic insurance coverage for those illnesses and individuals where the economic impact of a catastrophic illness could be tragic. All catastrophic coverage should have an appropriate deductible and co-insurance to make it economically feasible and to avoid abuse.
4. A program developed pursuant to those principles should be administered at the state level with national standardization through federal guidelines.

Dr. Van Syckle concluded his report by mentioning that the chiropractic suit in Pennsylvania had been settled and that the AMA had adopted a broader position on chiropractic at the Annual Convention.

Dr. Jerome K. Freedman informed the Council of a membership award plaque awarded CSMS by the AMA for having exceeded its prior year AMA membership in 1978. Drs. J. Alfred Fabro, William Whalen and Sidney Cramer also reported on their views of the AMA Convention.

A written report on several important actions taken at the meeting was submitted by the Executive Director, Mr. Norbeck.

In conjunction with the discussion of AMA membership in Connecticut, it was VOTED to direct a letter to the county medical associations urging local campaigns for improving AMA membership.

### Ad Hoc Committee on Medical Technology

Dr. Gerald O. Strauch, Stamford, addressed the Council on a proposal for establishing a Connecticut Medical Technology Information System. Following lengthy discussion of the proposal, it was VOTED not to appropriate the sum of $5,000. to help fund the initial working capital for the system.

It was further VOTED to approve the reappointment of an Ad Hoc Committee on Medical Technology, whose charge would be to make a library search of statistics on medical technology and with the material gathered set up a reference library in the CSMS building, and further that the Ad Hoc Committee be free to meet with other groups if they so desired.

Members appointed were Drs. Todd E. Anderson, Orvan W. Hess, Trudeau M. Horrax, Benjamin M. Shenker and James W. Tierney.

### Communication from Connecticut Chiropractic Association

It was VOTED to send the following letter to Marino R. Passero, D.C., President of the subject association:

The Council of the Connecticut State Medical Society discussed your June letter at its August 8, 1979 meeting. The Council reaffirmed its position, as stated to you in my earlier letter, that the Society does not prohibit physicians from releasing x-rays to chiropractors and does not prohibit physicians from accepting patients referred to them by chiropractors. Nor can the Society force physicians to do so. X-rays and x-ray reports relating to patients are made for the physician's own use in diagnosis and/or treatment of the patient. With the patient's written consent, a physician may permit x-rays or x-ray reports (or summaries of pertinent information in the reports) to be provided to by the patient (or the patient's designee which could include a chiropractor). It is the decision of each physician in each individual situation as to whether to accept a patient or to provide information with respect to a patient's condition. The Council of course expects all physicians to act in accordance with the law and in the best interests of their patients.

### Report of the President

Prior to his report, President Kamens asked that the Council accord Dr. Orvan W. Hess a standing ovation for his having been awarded the prestigious AMA Scientific Achievement Award and called attention to the lengthy article about Dr. Hess in the July 27 edition of American Medical News.

Dr. Kamens discussed the drop in AMA membership overall and specifically the low percentage of Connecticut physicians who have elected to join the AMA. It was VOTED to form an Ad Hoc Committee on Membership to be appointed by the CSMS President and Chairman of the Council, charged with the goal of attracting new members for the CSMS and the AMA.

President Kamens apprised the Council of Dr. Jerome K. Freedman's recent appointment by Governor Ella Grasso to the Connecticut Medical Examining Board. He and the Council joined in congratulating him for the appointment.

Dr. Kamens informed the Council of his recent meeting with Dr. Lawrence Pickett, Chairman of the Connecticut Medical Examining Board, in which a discussion was held regarding matters relating to the overall discipline of Connecticut physicians. He also reported that the professional liability proposal of

Harvey Wachsman, M.D., J.D., had been presented to the CSMS Committee on Professional Liability for consideration and study. Finally, Dr. Kamens expressed his opinion that it was most important for the Society to study the professional liability situation very carefully and to explore any and all viable alternatives.

### Organization of State Medical Association Presidents (OSMAP)

Dr. Jerome K. Freedman reported on his attendance at the OSMAP meeting in Chicago where he was elected Chairman of the organization.

### Reimbursement for Hospital Services

It was VOTED unanimously to have the Connecticut State Medical Society engage in a cooperative study with the insurance industry and the Connecticut Hospital Association in order to determine accurately the costs incurred by regulating the 35 hospitals in Connecticut.

It was VOTED further to authorize President Kamens at the next CSMS-CHA Joint Meeting to bring the motion before the leadership of the Connecticut Hospital Association, Mr. Jeffrey Goodwin of the Health Insurance Association and Mr. Vincent Messler of Connecticut Blue Cross.

### Committee to Study Perinatal Morbidity and Mortality

It was VOTED, with one member abstaining, to endorse the statement of the Committee to Study Perinatal Morbidity and Mortality amended as follows:

> "The decrease in fetal morbidity and mortality can be credited at least in part to fetal electronic heart rate monitoring. The appropriate use of fetal monitoring should be encouraged rather than discouraged. It is a valuable tool and should be utilized when indicated."

### Reports from Delegates to State Medical Societies

The reports from the delegates to the meetings of the Maine Medical Association (W. Raymond James, M.D.), Massachusetts Medical Society (W. Raymond James, M.D.), Medical Society of New Jersey (Sidney L. Cramer, M.D.), and Vermont State Medical Society (Frederick C. Barrett, M.D.) were received for information.

Dr. Cramer, based on his report on the meeting of the Medical Society of New Jersey, made a motion, which was tabled, that the matter for formulating a negotiating committee for negotiations at all levels of problems facing the CSMS be referred to the Committee on Statewide Medical Planning for study and report back to the Council. Dr. Kamens will be attending an AMA Negotiations Seminar in late August and will report on the conference at the next Council meeting.

### Life Members

It was VOTED to accept for information the following list of Life Members:

Anthony D'Angelo, Southington (H) - 1/1/79
J. Bainbridge Hanley, Bristol (H) - 1/1/79
Charles Ney, Stamford (F) - 1/1/79
Benjamin M. Shenker, Middletown (M) - 1/1/80

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on August 8, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

# In Memoriam

**BACHMAN, JOHN P.,** University of Buffalo, 1926. Dr. Bachman was a hospital administrator in the Hartford area since 1956. He served in the Medical Corps of the U.S. Army from 1926 and retired as a Colonel in 1956. Dr. Bachman died in La Jolla, California, at the age of 76.

**SMITH, FRED F.,** Howard University School of Medicine, 1930. Dr. Smith was a general practitioner in the New Haven area since 1933. He was a civic leader and principal founder of the Freddy Fixer improvement program and parade, and helped organize the Urban League of Greater New Haven and Community Progress, Inc. He served in World War II as a captain in the U.S. Army, and was emeritus professor of clinical medicine at the Yale University School of Medicine. Dr. Smith died July 23, 1979, at the age of 77.

**SPEIGHT, HAROLD E.,** Georgetown Medical School, 1927. Dr. Speight was an internist and cardiologist in the Middlesex area since 1928. In 1978 Dr. Speight marked his 50th year of practice in medicine. During his career, he served as senior attending physician of the Middlesex Memorial Hospital. He was chief of medicine at Middlesex from 1958 to 1968 and was a consultant in internal medicine at Connecticut Valley Hospital from 1941 to 1970. He was a consultant in cardiology at the Veterans Hospital in Rocky Hill from 1940 to 1951. He was co-founder of the Connecticut Society of Internal Medicine, and a former councilor to the Connecticut State Medical Society. Dr. Speight died August 17, 1979, at the age of 76.

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# PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

## OPPORTUNITIES FOR PRACTICE

(If no name is listed, contact the Physician Placement Service for more details.)

Office to share in New Haven Medical Building. Entire office facilities available every afternoon and two mornings per week. X-ray equipment. Send CV to CSMS/NS to be forwarded.

### ALLERGY

Wanted: Associate in extensive allergy practice in central Ct. Leading to partnership. Cert. in or elig. for cert. is desirable, but not necessary. 34 hrs./week; no evenings, no Saturday hours. Excellent salary with all fringe benefits, as well as two pension programs, with full funding. Excellent opportunity for family practice physician, internist or pediatrician who wishes a 9 to 5 position. Send inquiry to CSMS/Allergy-AAH.

### ANESTHESIOLOGY

To join group in 180 bed hospital in eastern Ct. Contact CSMS/Anes.-SGD.

### EMERGENCY ROOM

Emergency Physician full time to join ER Department staff that handles 52,000 visits per year in suburban 300 bed community hospital. Excellent salary, benefits and working conditions. Contact Robert Butterfield, M.D., Director of Emergency Services, Manchester Memorial Hospital, 71 Haynes Street, Manchester, CT 06040.

### FAMILY PRACTICE

Family Physician—bd. cert. or bd. elig. to join three other active family physicians in Central Ct. location. Newly equipped office, easy access to full service hospital. Good specialty services. Town of 60,000 with excellent access to recreational and cultural amenities. Incorporated. Excellent fringe benefits. Send inquiry to CSMS FP-FPA.

Family Practitioner or Internist: West Haven - office space. Ideal for either specialty. 1,300+ sq. ft., second floor. Pediatrician on 1st floor. Town of 55,000 near to Yale and Veterans Hospital. Call 934-7200.

### OBSTETRICS AND GYNECOLOGY

Looking for physician to share office and expenses with established internist in gorgeous rural community in south central Conn.—excellent opportunity for Ob/Gyn or pediatrician. Contact CSMS OB/GYN-CBM.

### PEDIATRICS

Well-established pediatric practice available immediately to Bd. Cert. or Elig pediatrician. Northeastern Ct. location. Arrangement negotiable. Send CV to CSMS/Pediatrics-JSL to be forwarded.

Community Health Services, Inc., a comprehensive neighborhood health center, is seeking 2 full time pediatricians. These individuals will join a professional provider staff consisting of 3 physicians, 4 nurse practitioners/physicians' assistants and will have ample opportunity for developing a fulfilling primary practice. Excellent salary and fringe benefits including malpractice insurance and pension plan. For further information contact: Mr. Thomas C. Watson, Administrator, Community Health Services, Inc., 520 Albany Avenue, Hartford, CT 06120. 203-249-9625.

## PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

### DERMATOLOGY

July '79. Age 31. Nat'l. bds., cert.-med., elig.-derm. MD: Univ of Pittsburgh. Int. and res.: Long Island Jewish Hosp. Also res.: SUNY and Univ. of Pittsburgh. Solo, grp. or assoc. practice desired in large or med. community in Ct. Contact CSMS/Derm.-DRB.

### FAMILY MEDICINE

July '80. Age 29. Nat'l. bds., elig. '80. MD: Jefferson. Res.: Geisinger Med. Ctr. Wishes grp. or assoc. practice in med. or small community. Harvey D. Cassidy, M.D., RD #6, Box 191, Danville, PA 17821.

Available now. Age 43. Presently in practice. Nat'l. bds., cert. MD: Univ. of Minnesota. Int.: St. Mary's, MN. Res.: Yale-New Haven Hosp. Desires grp. practice in Ct. Contact CSMS/FP-CM.

July '80. Age 30. Nat'l. bds., elig. MD: UConn. Int. and res.: Hunterdon Med. Ctr. Wishes grp. or assoc. practice in med. or sm. community in Ct. Nelson C. Walker, II, M.D., Rt. 31, Hunterdon Med., Ctr., Flemington, NJ 08822.

### INTERNAL MEDICINE

**Gastroenterology:** July '79. Age 31. Nat'l. bd., elig. MD: Emory. Int. and res.: Chanty Hosp.-Tulane. Fellowship: Westchester Cty. Med. Ctr. Wishes solo, grp. or assoc. practice in Ct. Bennett H. Bruckner, M.D., 192 Garth Rd., Scarsdale, NY 10583.

**Hematology-Oncology:** July '79. Age 35. Nat'l. bds., cert.-IM. MD: Taiwan. Int.: City Hosp., NY. Res.: Arthur Logan Mem. Hosp., NY and Kingsbrook Jewish Med. Ctr., Brooklyn, NY. Fellowship: Brookdale Hosp. Med. Ctr., NY. Wishes solo practice in large or med. community. Chi-Pui Cheung, M.D., 2074 20th Lane, Apt. 3G, Brooklyn, NY 11214.

July '80. Conn. license pending. Nat'l. bds., elig. MD: UConn. Int. and res.: SUNY-Upstate Med. Ctr. Special interest in gen. IM with participation in Primary Care Program in IM. Solo, grp. or assoc. practice in med. community. Longtime resident of Ct. John A. Collins, M.D., 505 Tilden Dr., Apt. 4, East Syracuse, NY 13057

**Internal Medicine/Pediatrics:** Oct.-Nov. '79. Age 34. Conn. license. Nat'l. bds., elig.-IM-Ped. MD: Univ. of Bologna. Int.-Ped.: Albany Med. Int.-Medicine: Wilson Mem. Hosp., NY. Res.: St. Mary's Hosp., Ct. Two years experience in ER. Relocation to Southwest area in assoc. with FP or Internist. Contact CSMS/IM-Ped.-RD.

**Cardiology:** Aug. '79. Age 32. Cert., elig.-card. MD: India. Int., res. and fellowship: Catholic Med. Ctr., NY. Solo, grp. or assoc. practice in large or med. community. Contact CSMS/IM-CARD.-POG.

**Rheumatology:** July '80. Age 30. FLEX. AB-cert.-IM; elig.-Rheum. MD, int., res. and fellowship: Johns Hopkins. Wishes grp or assoc. practice in large or med. community. Thomas J. Hirsch. M.D., 1444 Meridene Dr., Baltimore, MD 21239.

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## INTERNAL MEDICINE—CONTINUED

**Hematology:** July or Aug. '79. Age 29. FLEX. AB-cert. MD: India. Int.,res., and fellowship: Mt. Sinai Hosp., Hartford, Ct. Also fellowship: Univ. Hosp., Va. Wishes institutional, grp. or solo practice in Ct. Contact CSMS/IM-Hem.-RJ.

**Infectious Disease:** July '79. Age 29. Nat'l. bds., cert.-IM. MD: Albany. Int.: NY Hosp.-Cornell. Res.: Yale. Fellowship: Nassau Cty. Med. Ctr. Interested in high quality general IM also part-full time hospital based position perhaps with teaching or infection control responsibilities. Grp., assoc. or institutional practice desired in med. community. Contact CSMS/IM-Inf. Dis.-ALG.

**Rheumatology:** July '80. Age 30. Nat'l. bds., cert. MD: Cornell. Int. and res.: Albany Med. Ctr. Fellowship: Univ. of Pittsburgh. Wishes solo, grp. or assoc. practice in Ct. Christopher J. Lynch, M.D., 130 Stanton Court West, Pittsburgh, PA 15201.

**Hematology-Oncology:** July '79. Age 31. Nat'l. bds., elig. MD: New York Univ. Int., res. and fellowship: Metropolitan Hosp. Ctr., NY. Wishes grp. practice in med. community. Charles Masor, M.D., 3 Mountain Way S., West Orange, NJ 07052.

Available now. Age 33. Conn. license. AB-elig. MD: Albany. Int. and res.: St. Francis Hosp., Hartford, Ct. Wishes grp., institutional or industrial practice. Contact CSMS/IM-CBM.

**Hematology-Oncology:** July '80. Age 31. Nat'l. bds., cert.-IM, elig.-Hem.-Onc. MD: State Univ. of NY-Downstate. Int., res. and fellowship: Duke. Prefers hospital based, grp., or clinic practice doing predominantly hem-onc. Stuart H. Packer, M.D., 3406 Denise St., Durham, NC 27704.

**Oncology:** Available now. Age 33. Presently in practice. Nat'l. bds., cert. MD: Duke, Int.: Methodist Hosp., TX. Res.: Columbia-Presbyterian Med. Ctr. Fellowship: Duke-Hematology; Mt. Sinai Hosp., NY-Oncology. Wishes solo, grp. or assoc. practice. Carol D. Silver, M.D., 1619 Third Ave., Apt. 4G, N.Y., NY 10028.

**Pulmonary:** Sept. '80. Age 29. Nat'l. bds., cert. MD: NY Med. Coll. Int. and res.: Charity Hosp., New Orleans. Fellowship: Univ. of Texas. Wishes solo, grp. or assoc. practice in Conn. Contact CSMS IM-PUL./DAS.

## OBSTETRICS AND GYNECOLOGY

July '80. Age 28. Nat'l. bds., elig. '80. MD: Columbia. Int. and res.: Cedar Sinai, CA. Wishes large grp. or HMO in Ct. Stu Kalmanowitz, 1700 Manning Ave., #2, Los Angeles, CA 90024.

## OPHTHALMOLOGY

July '80. Age 30. Conn. license. Nat'l. bds., elig.-12/79. MD: Georgetown. Int.: Hartford Hosp. Res.: Univ. of Iowa. Wishes solo or assoc. practice in med. community. Thomas F. Carroll, M.D., 1022 Wylde Green Rd., Iowa City, IA 52240.

July '79. Age 34. Conn. license. AB-elig. MD, int. and res.: India. Fellowship: Univ. of Washington and UConn. Will consider all types of practice in med. community. Raj K. Singla, M.D., 124-J, 82 Brittany Farms Rd., New Britain, CT 06053.

## OTOLARYNGOLOGY

July '80. Age 27. Nat'l. bds., elig.-7/80. MD: Albert Einstein Coll. of Med. Int.: Montefiore Hosp. and Med. Ctr. Res.: Greater Baltimore Med. Ctr. Interested primarily in general ENT. Prefers western Ct. area. Med. community. Dean A. Schaffer, M.D., 6914 Lachlan Circle, Baltimore, MD 21239.

## PATHOLOGY

July '79. Age 34. FLEX. AB-elig. MD: Yonsei Coll. of Med. Int.: Westchester County, NY. Res.: Baptist Mem. Hosp., TN. Presently in practice. Wishes grp., assoc. or institutional practice in Ct. K.S. Kim, M.D., 3639 Outland Road, Memphis, TN 38118.

July '79. Age 39. Nat'l. bds., cert.-anatomical and clinical. MD: Tehran Med. School. Int.: Hackensack Hosp. Res's.: Christ Hosp., NY: Hahnemann and Baystate Med. Ctr., Mass. Fellowship: Magee Women's Hosp., PA. Wishes assoc. practice in med. community. Nematollah Mirzabeigi, M.D., 603-B, S. Trenton Ave., Pittsburgh, PA 15221.

## PEDIATRICS

Ped.-Adolescent Med.: July '80. Age 28. Nat'l. bds., elig. MD: Albert Einstein Coll. of Med. Int., res. and fellowship: Long Island Jewish Hosp. Interested in ped. or adolescent med. or preferably a combination thereof in a grp., assoc. or institution. Large or med. community. Martin M. Fisher, M.D., Adolescent Clinic, Long Island Jewish Hosp., New Hyde Park, NY 11040.

**Ped. Cardiology:** July '79. Age 31. Nat'l. bds., cert. ped., elig.-Ped. Card. Presently in practice. MD: UConn. Int.: Mercy Hosp., Ca. Res.: Georgetown. Fellowship: Univ of Colorado. Wishes grp., assoc. or institutional type practice in large or med. community. Edward P. Hargus, M.D., 12909 Calle De Las Rosas, San Diego, CA 92129.

Dec. '80. Age 33. AB-elig. MD: Stanley Med. Sch., India. Int: Franklin Sq. Hosp., MD. Res.: Univ. of MD. Will consider solo, grp., assoc., county health clinic or HMO. Suryakumar Rajaram, M.D., 24 Wendy Lane, Charleston, SC 29407.

Nov. '79. Age 30. FLEX. Am. Bds.-elig. MD: India. Res.: 1st yr., Kings Cty. Hosp., NY; 2nd yr., Wyckoff Heights Hosp., NY; 3rd yr., Lincoln Hosp., NY. Will consider all types of practice in any size community. Contact CSMS/PED.-TGT.

## SURGERY

July '80. Age 34. Am. Bds., elig. MD: Cairo. Int.: Worcester City Hosp., MA. Res.: Methodist Hosp., Brooklyn. Fellowship: Downstate. Will consider all types of practice except institutional in any type of community. Aly Bassal, M.D., 514 5th St., Brooklyn, NY 11215.

**Gen., Vas. & Thor.:** Available now. Age 39. Am. Bds.-cert. Presently in practice. MD: Univ. of Michigan. Int.: Univ. of Nebraska Hosp. Res's.: Univ. of Rochester and Univ. Hosp. of Cleveland. Wishes grp. or assoc. type practice in large community in Conn. Contact CSMS/Surg.-RMK.

Aug. '79. Age 30. Nat'l. bds., elig. MD and res. at NJ Med. School. Presently instructor in General Surgery at NJ Med. School. Wishes western portion of Ct., in solo, grp. or assoc. practice. Bruce A. Marshall, M.D., 73 Campbell Ave., Clifton, NJ 07013.

**Cardio-vascular, thoracic, general and transplant:** July '80. AB-cert.-GS, elig.-cardiac. MD: Univ. of Natal. Int.: King Edward Hosp., both in S. Africa. Res.: GS-Einstein Hosp.; transplant Columbia Presbyterian; cardio-vascular and thoracic—Case Western. Will consider all types of practice except industrial in large or med. community. S.A. Paruk, M.D., 3131 Whitethorn Rd., Cleveland Heights, O 44118

## UROLOGY

July '80. Age 31. Nat'l. bds., elig. MD: Chicago Med. Sch. Int.: St. Elizabeth's Hosp., Boston. Res's.: Beth Israel Hosp., NY and NY Univ. Wishes grp. or assoc. type practice in Ct. Philip L. Miller, M.D., 333 E. 30th St., Apt. 18B, N.Y., NY 10016.

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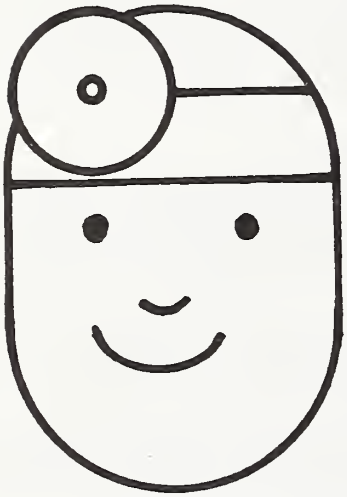

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**References:**
1. Meyer, C.: American Folk Medicine. Scarborough, New York, Plum Books — New American Library, 1975, p. 208.
2. Data on file, MERRELL-NATIONAL LABORATORIES
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# Colorectal Cancer: Current Diagnostic Approaches and Strategies for Management

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Excluding skin cancer, colorectal cancer is the most prevalent cancer in the United States with an estimated 112,000 new cases in 1979.[1] Large bowel cancer is the second leading oncologic cause of death, with bronchogenic cancer heading the list.[1 2] Mortality from colorectal cancer for 1979 is estimated at 24,900 deaths in males and 27,000 deaths in females.[1] Age-adjusted cancer death rates in the United States expressed per 100,000 population have varied little since 1930 with rates in males of 15 in 1930, 20 in 1950 and 19 in 1979 and corresponding rates in females of 17, 19, and 15.[1] The incidence rate of colon cancer in American whites was formerly much higher than in American blacks. Now similar incidence rates are being found in white and black females while the rate in black males is approaching that in white males.[2] Improved reporting of cancer statistics probably explains much of this apparent trend, although dietary factors may be important. Five year survival rates from the time of diagnosis for all stages of disease are poor with a 44% survival rate in males and 46% in females.[1] This review will summarize the known risk factors promoting colorectal cancer, will discuss methods for the diagnosis of both early and late disease and will highlight current therapeutic strategies in the management of the patient with colorectal cancer.

### Risk Factors

Although the cause of colorectal cancer is unknown, it has been observed that males and females are affected in a 1:1 ratio for colon cancer and a 1.4:1 ratio for rectal cancer. Colorectal cancer is unusual below age 40 if patients with inflammatory bowel disease and inherited polyposis syndromes are excluded from analyses. The peak incidence of colorectal cancer is at age 75. Patients with a history of a prior colorectal neoplasm, breast cancer or female genital tract cancer have a higher risk for the subsequent development of a colorectal cancer.[3] Likewise, recent findings indicate that familial associations in colon cancer are higher than in control groups. In some families there is an increase in the number of deaths due to colorectal cancer among first degree relatives of the index cases compared to the expected incidence.[4] Studies of the histopathology of polyps, the natural history of the inherited gastrointestinal polyposis syndromes and inflammatory bowel disease, and evaluation of dietary factors offer insights into the possible etiologies of colorectal neoplasia.

### Sporadic Polyps

A polyp is a growth or tumor raised up above its surrounding mucous membrane.The terminology used to describe polyps and relate them to cancer is confusing. One can use anatomical descriptive terms such as sessile, pedunculated or plaque-like, but these terms do *not* relate to the incidence of cancer in association with the polyp.[5] An alternative system of

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Table I

HISTOPATHOLOGIC TYPE OF EPITHELIAL COLORECTAL POLYP AND PROBABILITY OF ASSOCIATED CARCINOMA[5]

| | *Histology* | *Synonyms* | *Percentage with Associated Carcinoma* |
|---|---|---|---|
| | Hyperplastic polyp | Metaplastic | 0 |
| polyps with neoplastic potential | Adenomatous polyp | Tubular; glandular adenomas | 4.8 |
| | Villoglandular polyp | Tubulovillous; papillary; mixed adenomas | 22.5 |
| | Villous adenoma | Villous papilloma | 40.7 |
| | Polypoid cancer | | 100.0 |

nomenclature is summarized in Table I and attempts to relate the histology of the polyp to the probability of an associated overt or in situ carcinoma, a concept known as the adenoma-carcinoma sequence.[5] [6] About 75% of all polyps are adenomatous while slightly less than 10% are villous adenomas.[5] Although polyps less than 1 centimeter (cm.) in diameter have a small chance of harboring a carcinoma, villous adenomas of less than 1 cm. have an almost ten-fold increased risk of cancer compared to adenomatous polyps of similar size (9.5% vs. 1.0%).[5] This finding stresses the need for removal and histologic examination of all polyps. At best, fulguration should be reserved for polyps less than 1 cm. in size. For polyps greater than 2 cm. in diameter, the risk of associated carcinoma is somewhat greater for villous adenomas (52.9%) then for villoglandular polyps (45.8%) and adenomatous polyps (34.7%), but between 1-2 cm. the risk of associated carcinoma for the three histologic types is not significantly different.[5] It might appear that the higher malignancy rate for villous adenomas relates to their usual larger size. However, the cytologic grade of atypia even when size is taken into account appears to be a major determinant of ultimate malignancy. Villous adenomas tend to have a greater proportion of moderate and severe cytologic atypia than do adenomatous polyps.[5]

Available information would thus suggest that cytologic atypia, polyp size and polyp histology are all important in the so-called adenoma-carcinoma sequence. For colorectal carcinoma to occur, adenomatous polyps do not transform into villoglandular adenomas nor do villoglandular adenomas transform into villous adenomas. It does appear that villous adenomas have a greater potential to give rise to invasive cancer, perhaps because of their larger size and more severe cytologic atypia. Indirect evidence obtained from age distribution curves for adenomatous polyps, adenomas and carcinoma suggest that for those neoplastic polyps which eventually give rise to carcinoma, an average of not less than 4-5 years is involved in the adenoma-carcinoma sequence and perhaps as long as 10-15 years.[5] [6]

It has been suggested that as cancer spreads through the bowel wall, it first expands on the mucosal surface and tends to destroy the surviving neoplastic polyp. The frequency with which a neoplastic polyp and invasive cancer are found together varies with spread of the cancer component. With cancerous invasion of only the submucosal tissues the frequency is 60%, with spread in continuity limited to the bowel wall the frequency is 20% and with extramural growth the freguency is 7%.[6] This observation suggests that one-half to perhaps two-thirds of invasive cancer arises from neoplastic polyps. Presumably the remainder of invasive cancer arises de novo from colonic epithelium but this point remains controversial.[7] [8]

Patients who have had a resection of one malignant tumor from the large intestine are at risk for the subsequent development of a second primary large intestinal tumor.[9] [10] This risk is greatest if a neoplastic polyp was evident in the initially resected specimen.

## Polyposis Syndromes

Several well-defined inherited gastrointestinal polyposis syndromes have recently been reviewed.[11] [12] Their salient features are described below and summarized in Table 2. Familial polyposis (familial adenomatous colonic polyposis) is an autosomal dominant syndrome with incomplete penetrance characterized by hundreds to thousands of small adenomatous polyps in the colon and rectum and the lack of extracolonic manifestations. Historical data suggest that patients present with polyposis alone at an average age of 27, and with polyposis and carcinoma at an average age of 39.[5] [12] Half of the patients at the time of diagnosis of invasive cancer have multicentric cancerous lesions. Treatment should be total colec-

Table 2

INHERITED GASTROINTESTINAL POLYPOSIS SYNDROMES

| *Polyposis Syndrome* | *Inheritance* | *Location of polyps* | *Pathology of polyps* | *Population at risk* | *Extraintestinal manifestations* |
|---|---|---|---|---|---|
| Familial polyposis | Autosomal dominant | Colon, rectum | Adenomatous | >80% of untreated patients | None |
| Gardner syndrome | Autosomal dominant | Colon, rectum; rarely in small intestine, stomach | Adenomatous | High as in familial polyposis; increased risk of pancreatic, ampullary, duodenal carcinoma as well | Osteomas, fibromas, lipomas, desmoids |
| Juvenile polyposis | Autosomal dominant | Colon, rectum; occasionally in small intestine, stomach | Hamartomatous | Probable increased risk of stomach, duodenal, pancreatic, colonic carcinoma | None |
| Peutz-Jeghers | Autosomal dominant | Small intestine; commonly in stomach, colon rectum | Hamartomatous | Probable increased risk of cancer often involving stomach and duodenum | Melanin spots on eyelids, lips, buccal mucosa, digits, anus |

tomy once the diagnosis of familial polyposis has been made because of the high risk of cancer even in children less than age 16.[11] Two approaches to the management of the rectum as a site of cancer have been advocated: total proctocolectomy, and total colectomy with an ileorectal anastomosis. Routine proctoscopy at 6 month intervals with surgical removal and/or electrocoagulation of developing polyps must be performed if the rectum is left intact. The risk of cancer in the rectal segment is unclear as two large series are at extreme variance with each another reporting cumulative risks at 20+ years of 3.6% vs. 59%.[5 11]

The Gardner syndrome is characterized by an autosomal dominant pattern with incomplete penetrance and colorectal findings similar to the familial polyposis syndrome. In Gardner's syndrome there are fewer polyps, often extracolonic benign soft tissue and osseous tumors and a higher incidence of neoplasms arising in the pancreaticoduodenal region.[13 14] Management is similar to that of patients with the familial polyposis syndrome.

Juvenile polyposis is an autosomal dominant syndrome with a high degree of penetrance characterized by hamartomatous polyps in the colon and rectum and less commonly in the stomach and small intestine. It has been recently suggested that there is an associated high risk for the development of stomach, duodenal, pancreatic and proximal colon carcinoma.[15] Treatment is conservative with resection of polyps as indicated by the individual patient's clinical condition.

The Peutz-Jeghers syndrome is characterized by hamartomatous polyposis always involving the small intestine and often involving the stomach, colon and rectum. Extraintestinal manifestations of this autosomal dominant disorder may include melanin spots on the eyelids, lips, buccal mucosa, digits and anus. The risk of associated gastrointestinal cancer is 2-3% with the malignancy commonly arising in the stomach or duodenum.[16 17] Management should include resection of all gastric and duodenal polyps, symptomatic polyps and polyps of large size.

Other rare syndromes of inherited gastrointestinal polyposis include Turcot's syndrome (adenomatous polyps and gliomas of the brain) and Oldfield's syndrome (polyps and sebaceous cysts).

### Inflammatory Bowel Disease

Crohn's disease of both the small and large intestine is associated with an increased risk of adenocarcinoma.[18 19] Most cases of carcinoma have occurred in patients with long-standing disease. Of interest is the fact that the majority of small bowel carcinomas arising in the setting of Crohn's disease are in the jejunum and ileum, as opposed to the expected higher incidence in the duodenum.[20] The distribution of adenocarcinoma of the colon superimposed on Crohn's colitis is also reversed with the majority of the carcinomas arising in the proximal and transverse colon instead of the expected 70% occurrence in the descending colon, sigmoid and rectum. The increased risk for the development of carcinoma in patients with Crohn's disease is unknown at present but may be as high as twenty times that of a control population.[19]

The cumulative risk of colorectal cancer in patients with ulcerative colitis is between 3 and 5%. This risk increases markedly after 10 years from initial diagnosis,[21] in patients with extensive colitis and in patients with chronic continuous disease.[5] The role of total proctocolectomy in the management of patients with long-standing ulcerative colitis remains controversial.[5 21]

### Diet

Epidemiologic studies have demonstrated a low incidence of large bowel cancer in Japan, parts of Asia and Africa, and most of South America with the exception of Uruguay and Argentina. The incidence of colorectal cancer is high in the United States and in Western Europe.[22] [23] Large bowel cancer is more prevalent in Japanese who have emigrated to the United States compared to Japanese living in Japan, and is more prevalent in American blacks compared to African blacks.[22] [23] Potential factors that individual investigators have suggested as predisposing to a high incidence of colon cancer include high dietary fat content, use of refined sugar and the lack of dietary fiber.[24] [25] Dietary fats may directly alter the intraluminal concentrations of bile acids, cholesterol and their metabolites. These metabolites may secondarily affect the activity of colonic bacteria leading to the bacterial production of carcinogens. However, in humans no specific carcinogen has been identified to date despite the large body of experimental data in both animals and humans suggesting that bile acids, cholesterol metabolites, aromatic amines and nitrosourea derivatives are potentially carcinogenic.[24]

### Diagnosis

Early diagnosis of colorectal carcinoma is clearly the key to improving survival and cure rate of patients.[26] Nearly all asymptomatic patients in whom colorectal cancer is detected have localized disease (less than 4% have distant metastases) and, therefore, are potentially curable with surgery. In fact the 5 year survival rate in this group approaches 90%.[27] This compares favorably with the overall 5 year survival rate of only 44%, and even the 71% rate for localized disease.[1] Thus, the key to better results lies in making the diagnosis while the patient is asymptomatic, and this means some form of screening.

### Screening

The fact that colorectal cancer is a slowly progressive disease with a long asymptomatic period, provides an opportunity for early diagnosis by periodic examinations.[28] This may take the form of organized mass screening,[29] a cancer detection clinic[30] or the periodic complete health examination by the patient's primary physician.

A variety of techniques have been evaluated for screening. The most economically sound and cost-effective procedure is the test for occult blood in the stool. In selecting from among the tests for occult blood, one wants a test [31] that is highly specific, limited in sensitivity so that false positives are minimized and highly reproducible. Compared to $^{51}$Cr-labeled red cells, guaiac reagent and orthotolidine (Hematest®) tablets were extremely sensitive but yielded false positive reaction rates of 72% and 76% respectively on the 240 specimens compared.[32] A modified guaiac test (Hemoccult®) exhibited a false positive rate of 12%.[32] Hemoccult is approximately one-fourth as sensitive as guaiac and Hematest but could miss lesions with low rates of bleeding unless multiple stools are tested. A positive Hemoccult test usually indicates a significant gastrointestinal bleed and at present seems to be the test of choice provided that at least three stools are tested to minimize false negative results. Some authors find that detection of lesions is improved by the ingestion of dietary roughage during the four day period of stool collection.[32] [33] False positives may be reduced by the use of a meat-free diet whenever a positive is detected.[34] The manufacturer is now offering Hemoccult II® as a card with three double slides and sticks, and a mailing envelope. The patient is instructed to prepare two stool specimens from different parts of the stool from three consecutive bowel movements. Thus, the physician will receive and develop six slides. Since the test really detects the peroxidase enzyme associated with hemoglobin, the patient is advised to eat no "red" meat, turnips or horseradish during the test period.

It should be unnecessary to remind physicians that a physical exam is not complete if a digital examination of the rectum has been omitted, as it too often is neglected. The digital exam may detect a tumor in the prostate, in the rectal mucosa, in other pelvic organs, and it usually yields a specimen of stool for another test for occult blood. Abdominal palpation reveals tumor only when it is very large and widespread.

### Proctosigmoidoscopy

There is a large and controversial literature regarding the utility and cost-effectiveness of routine proctosigmoidoscopy. For the asymptomatic patient with no increased risk factors, the earlier recommendation for proctosigmoidoscopy every year after age 40 is being discarded because the cost is between $10,000 and $70,000 spent per case of cancer found.[30] A more realistic recommendation is proctosigmoidoscopy every two years after age 50.[35] In the high risk patient, that is, one with a positive family history for colorectal carcinoma, known polyps, a family polyposis syndrome, inflammatory bowel disease, proctosigmoidoscopy is indicated at much younger age and on a yearly basis. The value of routine proctosigmoidoscopy must be evaluated on a risk-benefit basis for each patient. A study at the University of Minnesota[36] picked up eleven asymptomatic carcinomas of the colon in 103,645 routine examinations. Unfortunately, there were five perforations above the peritoneal reflection which required abdominal exploration and repair. The procedure was beneficial to the eleven patients with unsuspected colon cancer, but it was a disaster for the five asymptomatic patients who had a perforation above the peritoneal reflection. With the new flexible fiberoptic colonoscope it is hoped that a greater part of the colon can be visualized at less risk to the patient.

### Barium Enema

Although some executive screening programs still employ a barium enema as a routine study, it is much too costly and time-consuming. It is often of suboptimal value because of poor patient preparation or omission of air contrast techniques. The value of the barium enema is realized in the high risk patient, the symptomatic patient or in the patient scheduled for a colonoscopy. Blind areas occur in every patient colonoscoped, especially in the rectosigmoid, and the splenic and hepatic flexures. The barium enema is an uncomfortable and unesthetic procedure but of low risk and moderately high specificity and accuracy.

### Colonoscopy

The advent of the flexible fiberoptic colonoscope has revolutionized diagnostic and therapeutic capabilities in the evaluation of high risk and symptomatic patients. It extends the area of direct observation from 25 cm. to the entire colon, which can be visualized in 80% of patients.[37] Through the colonoscope, diagnostic or excisional biopsy can be performed, as well as target brushing and cytology.

Colonic lavage cytology gained popularity in only a few institutions which set up specific programs directed to that diagnostic modality. It has proven to be tedious, expensive and not esthetically pleasing. However, jet stream lavage cytology through the colonoscope for an already prepared bowel, is beginning to revive in interest and popularity as it is simple and effective.[38] It is particularly useful in patients with premalignant lesions like ulcerative colitis or familial polyposis where single or multiple biopsies are negative. Rare false positives occur in less than 1% of patients in experienced hands.

### CEA and Tumor Markers

The introduction of the test for carcinoembryonic antigen (CEA) in 1965 heralded an extensive study of tumor-associated antigens as clinically useful diagnostic markers in human cancer.[39] Unfortunately that promise has not been realized yet. It is now known that the antigen is found in normal serum, in normal adult colon tissue, in other primary gastrointestinal malignancies, in cirrhosis, in pancreatitis, in inflammatory bowel disease and in heavy smokers. It is not a sensitive test for the early detection of colonic cancer.[40] It may be more related to vascular invasion or tumor necrosis than to the amount of tumor present. The test correlates roughly with the response to surgery, radiation and/or chemotherapy and is useful as a diagnostic adjuvant.[41] It is twice as sensitive as alkaline phosphatase for liver metastases from colonic carcinoma. However, it is not clear how reliable it is in following patients for recurrence. Some groups find it inadequate for early detection of recurrent tumor[42] and others use it for long term follow-up to predict tumor recurrence with a lead time of several months.[43]

Preoperative CEA levels have been found to be useful as a prognostic indicator in colorectal carcinoma. The recurrence rate was higher in patients with localized and regional disease who had preoperative CEA levels greater than 5ng. per milliliter. There was a linear inverse correlation between preoperative levels and estimated mean time to recurrence, ranging from 30 months for a level of 2 ng/ml. to only 9.8 months for a level of 70 ng/ml.[44] Some authors even use the CEA as a guide to the need for a second look operation or as an indication to begin chemotherapy.[45] Thus, the CEA is useful for following colorectal cancer but not for its diagnosis in the asymptomatic person.

### Clinical Presentations

Patients being evaluated for colorectal cancer may be grouped into four categories:

(1) Symptomatic
(2) Asymptomatic but with a premalignant condition
(3) Asymptomatic but at high risk
(4) Asymptomatic with a normal risk

The symptomatic patient may present with rectal bleeding, diarrhea, rectal discharge of mucus, tenesmus, abdominal pain, nausea, obstruction, anemia, distension, and/or constipation. The evaluation of such a patient should be expeditious and should include a test for occult blood, digital rectal exam, sigmoidoscopy, air contrast barium enema, and if any doubt remains about the diagnosis or location of lesions, a colonoscopy with biopsy or brushings. If carcinoma is found, attempts to document metastases are indicated and might include a bone scan, liver scan, ultrasound of the liver, chest xray, CEA and liver-associated chemistries. Surgery may be indicated for a curative or palliative result depending on staging.

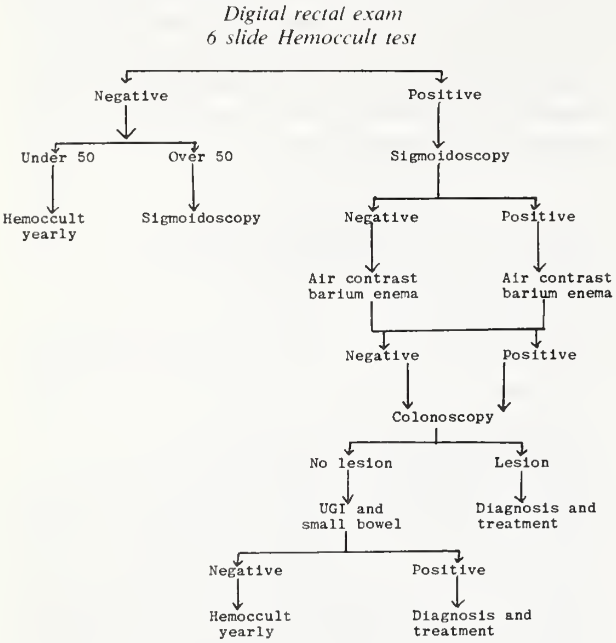
The asymptomatic patient with a premalignant condition could have the test for occult blood omitted as it is usually positive.[37] Such a patient should have sigmoidoscopy, barium enema and colonoscopy possibly with lavage cytology at appropriate intervals depending on the length of time the underlying premalignant condition has been present.

The asymptomatic patient at high risk is one who has a family history of single or multiple primary carcinomas of the colon, has had multiple cancers in different anatomic sites (ovary, breast, colon, uterus) is a relative of patients with polyposis syndromes or is a patient with previous colon polyps or cancers. These individuals should be followed at intervals with Hemoccult slide testing, a digital rectal exam and a sigmoidoscopy. Those with polyps or cancers should have a barium enema yearly if over age 40 and with no plans for child bearing. A colonoscopy would be done only if one of the earlier tests had been positive or unsatisfactory.

The asymptomatic adult patient with no risk factors should have a yearly Hemoccult test with six slides on three separate specimens. A digital rectal exam is also indicated. Over the age of 50, a sigmoidoscopy is probably indicated every second or third year. Further

Table 3

SCREENING FOR COLORECTAL CANCER



testing would depend on the findings and any index of suspicion.

Table 3 summarizes the screening procedures for patients with possible colorectal cancer.

### Surgery

Surgery is the only means by which colorectal carcinoma is now cured. The depth of cancerous invasion into the bowel wall and the presence of nodal metastases directly affect the surgeon's ability to prevent recurrent disease. The Dukes pathologic staging system (Table 4) as modified by Kirklin[46] and later Astler and Coller[47] has provided a useful classification for predicting patient groups at high risk for relapse following surgery.

Carcinoma confined to the mucosa or submucosa (stage A) has a 5 year survival ranging from 74-100%,[47] [48] penetration into the muscularis with negative nodes (B1) reduces the 5 year survival to 60-65%[47] while penetration into or through the serosa with negative nodes (B2) leads to a 5 year survival of 40-60%.[49] Regional lymph node involvement is seen in over 50% of cases at surgery[50] and further reduces the 5 year survival to approximately 30%.[49] The number[48] and location[51] of the lymph nodes has also been shown to adversely affect prognosis. The location of the primary influences prognosis with survival being 10-15% less in extraperitoneal rectal lesions as compared to lesions above the peritoneal reflection similarly staged.[52]

Unlike other solid tumors such as breast carcinoma and malignant melanoma which may have late relapses, recurrences in colorectal carcinomas usually occur within five years from definitive treatment. Death in colorectal carcinoma is related to local recurrence in one-half the patients and distant metastases in the other half.[53] Liver metastases are present at initial surgery in 15-25%[54] and at autopsy in 64%[48] of patients. The other frequent sites of distant spread, include lung metastases (20-30%), bone, ovaries and brain (10% or less).[48]

Survival from proof of recurrence or unresected primary is short. Moertel reported a median time of seven months with 10% or patients alive at 18 months.[55] In those patients with liver metastases, the median survival is approximately 5 months.[56] As can be seen from the above survival figures, once there has been a recurrence the chances for cure are remote.

### Radiation Therapy

Radiation therapy has been proven effective for symptomatic palliation in inoperable or recurrent rectal carcinoma.[57] The role of radiation in resectable rectal carcinoma also appears promising. A study conducted by Kligerman and associates at Yale[58] randomized patients with potentially curable adenocarcinoma of the rectum or rectosigmoid to 4400-4600 rads over 4½ weeks followed by resection 4 weeks later, or to resection alone. Patients given preoperative irradiation had nodal involvement in only 3 of 13 cases versus 11 of 16 treated by surgery alone. Survival in this small series was improved in the irradiated group. The Veterans Administration Surgical Adjuvant Group's randomized study of preoperative irradiation (2000-2500 rads in 2 weeks) (59) showed a survival advantage at 5 years for the irradiated group (40.8% vs. 28.4%), only in those patients undergoing an abdominoperineal resection. There are a number of ongoing cooperative group studies evaluating the role of pre and postoperative irradiation alone and in combination with chemotherapy in the therapy of resectable rectal carcinoma.[60] It is certainly hoped that current studies will substantiate the effectiveness of irradiation as an adjunct to surgical resection of rectal cancer.

### Chemotherapy

The role of chemotherapy in metastatic colorectal cancer has been widely investigated. Results to date

Table 4

MODIFIED DUKES STAGING SYSTEM FOR COLORECTAL CARCINOMA[47]

| | |
|---|---|
| A | Limited to mucosa or submucosa. |
| B1 | Extension into but not through the muscularis; negative nodes. |
| B2 | Extension to or through the serosa; negative nodes. |
| C1 | Extension into but not through the muscularis; positive nodes. |
| C2 | Extension into or through the serosa; positive nodes. |
| D | Distant metastases or liver involvement by tumor. |

using many drugs and combinations have not shown any significant benefit over single agent 5-fluorouracil therapy.[61] The activity of 5-fluorouracil is 21% in over 2000 patients.[62] Of the drugs felt by Moertel[61] to have activity in this disease, namely fluorinated pyrimidines (5-fluorouracil, ftorafur and 5-fluoro-2-deoxyuridine), nitrosoureas (BCNU, CCNU, and methyl CCNU), mitomycin C, triazinate (Baker's antifol) and ICRF-159, none has exceeded the response rate of 5-fluorouracil as initial treatment.[61] Combination chemotherapy utilizing 5-fluorouracil, methyl CCNU and vincristine was initially reported as having a 40-43% response rate.[63] [64] However, additional patient accrual on Moetel's study[64] has reduced the response rate to 27% of 137 cases[61] and there has been no survival advantage over 5-fluorouracil therapy alone. Several additional studies have also failed to demonstrate a significant benefit for 5-fluorouracil-methyl CCNU drug combinations in the treatment of patients with large bowel carcinoma.[65-68]

The role of adjuvant chemotherapy in high risk (Dukes B2 and C) patients after a curative resection remains undefined. The Veterans Administrations Surgical Adjuvant Group (VASAG) in two trials, using 5-fluorouracil for 2 courses postoperatively or for every 6 weeks for 18 months post-curative resection has shown a marginal but not significant benefit for the 5-fluorouracil treated groups.[69]

In the VASAG study with two postoperative courses of 5-fluorouracil there was a 58.5% 5 year survival in the treated group vs. 49.4% in the control group.[69] In the prolonged intermittent trial the percentages were 48.9% and 44.2% favoring 5-fluorouracil.[69] Other surgical adjuvant studies using nitrogen mustard[70] thio-TEPA[71], or intraluminal 5-fluorouracil at surgery[72] have been negative. Currently there are a number of ongoing adjuvant chemotherapy trials in colorectal carcinoma, and fortunately a number have included a control arm with surgery alone.[60] It is only through well designed and managed clinical studies that the future role of chemotherapy in helping to cure or palliate colorectal carcinoma will be known.

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# Small Cell Malignant Tumors of Childhood: Clinically Presenting as Inflammatory Bowel Disease

MARIA J. MERINO, M.D. AND VIRGINIA A. LIVOLSI, M.D.

**ABSTRACT—We present four children with tumors involving the small intestine each of whom initially was considered to have inflammatory bowel disease. The clinical and pathologic features of these cases are discussed, to reiterate the necessity of early diagnosis.**

Although "small round cell tumors" are encountered commonly in the pediatric age group, involvement of the small intestine is unusual.[1] Primary malignant lymphomas of the gastrointestinal tract occur infrequently in childhood.[2 4] In addition, extension of metastasis of primary retroperitoneal neoplasms presenting as a bowel lesion is rare.

Because both clinicians and pathologists may be unfamiliar with these unusual presentations, misdiagnosis leading to treatment delays may occur.

We have encountered three cases of primary malignant lymphoma and another of metastatic neuroblastoma of the small bowel in children, each of which was initially diagnosed clinically as inflammatory bowel disease. We report them here, in an attempt to bring attention to the problem.

### Case 1

A 7-year-old white male was admitted for the first time to Yale-New Haven Hospital with an eight-day history of intermittent abdominal pain and vomiting. He denied fever, diarrhea or bloody stools.

Past medical history included an inguinal hernia repair at 1½ years of age.

Physical examination disclosed a well-developed, white male with a diffusely tender abdomen, positive rebound sign and moderate spasm of both recti muscles. Shotty anterior cervical nodes were palpable.

Laboratory data included a leucocyte count of 11,200 (with 86 segmented forms and 7 bands), hematocrit 34.5, hemoglobin 11.6, and normal electrolytes. Urinalysis showed 2+ glucose; ketones and trace occult blood were present. The initial diagnosis at the time of admission was acute appendicitis; inflammatory bowel disease was considered less likely.

At exploratory laparotomy the surgeon described "classic" regional enteritis, with mural thickening of the terminal ileum and mesenteric adenopathy; however no biopsy was taken at this time.

Four days after surgery, sigmoidoscopy and rectal biopsy were performed. The mucosa was described as normal; biopsy confirmed this. Thus the patient was considered to have small bowel Crohn's disease, was treated with azulfidine and discharged on the eighth postoperative day.

Three days after discharge, he came back to the hospital with complaints of nausea and bilious vomitus. Abdominal films revealed obstruction of the ascending colon by a mass which was interpreted as the wall of an abscess. At this time it was decided to treat the child conservatively with nasogastric suction and medications which included ACTH, Azulfidine, prednisone (40mg) and fiber-free diet. He improved and was discharged.

A few days later, he was readmitted with nausea and vomiting, but he did not respond to conservative therapy. At this time, a large mass could be palpated in the right lower quadrant of the abdomen. Repeat laparotomy found a large mass in the cecum. A ileocolectomy with ileostomy was performed.

The surgical specimen consisted of a 45 cm segment of ilem, ascending colon and appendix.

On opening the specimen, a 7 x 5 x 4 cm cauliflower-like ileal mass was found protruding into the lumen of the cecum and compromising the lumen of the appendix. Enlarged mesenteric lymph nodes were present. Histologically, the tumor was composed of small round hyperchromatic cells with scanty cytoplasm. The tumor extended through all layers of the bowel wall and involved the mesenteric lymph nodes. The margins of resection showed serosal involvement by tumor infiltrate. A diagnosis of malignant lymphoma, poorly differentiated lymphocytic type (Rappaport classification)[5] was made.

Radiation therapy was started; he received 1800 rads to the abdomen. Therapy was interrupted because staging workup demonstrated widespread disease with involvement of abdominal, mediastinal and peripheral lymph nodes as well as bone marrow. The patient deteriorated and died one week after admission with pneumonia, sepsis and terminal renal failure. Autopsy permission was not obtained.

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## Case 2

This 6-year-old white female was admitted to another hospital with the chief complaints of abdominal pain and vomiting. For several months, she had noted mild abdominal pain, usually prior to bowel movements.

Physicial examination disclosed a well-developed and nourished six-year-old girl in no apparent distress. Pertinent findings were limited to several enlarged nontender mobile mid-inguinal lymph nodes bilaterally, and one small node in the right anterior cervical triangle.

Significant laboratory data included a white blood count of 8,100 (with 45 segmented forms and 3 bands), 35 lymphocytes, and 9 monocytes, hemoglobin 12.6 and hematocrit 35.9. A barium enema showed ileal intussusception which was not reducible. The preoperative diagnosis was believed to be recurrent episodes of intussusception, or ileitis.

At operation a large intraluminal ileal mass was found associated with enlarged mesenteric nodes. An ileal resection was undertaken.

The surgical specimen consisted of a 10 cm segment of small bowel which exhibited in its mucosa a concave grayish-white necrotic growth of approximately 2.5 cm. Two enlarged lymph nodes were also noted.

Histologically the tumor was composed of small hyperchromatic malignant cells that extended throughout all layers of the bowel wall and involved two mesenteric nodes. Diagnosis of diffuse malignant lymphoma, poorly differentiated lymphocytic type, was made (Rappaport).[5] Some tumor cells disclosed plasmacytoid features. No serum immunoglobulin abnormalities were recognized.

The patient was then admitted to Yale-New Haven Hospital for further evaluation and therapy. Physical examination was unremarkable, except for the previously noted lymphadenopathy.

Workup including liver and spleen and bone scans, lymphangiogram, intravenous pyelogram, upper gastrointestinal series, and bone marrow aspirates and biopsy disclosed no evidence of tumor. Therefore, the patient was staged as IE (extra nodal). Two years after diagnosis and surgery the patient remains free of disease.

## Case 3

A 10-year-old white male was admitted to Yale-New Haven Hospital with the chief complaint of continuous vomiting for three days.

According to the mother, the child had been having watery diarrhea episodes between the ages of 7 months and 1 year, at which time, he was seen in another institution and was diagnosed as having a "digestive defect"; this was not characterized further and no special diet or medications were given.

Two years prior to this admission he was seen and evaluated in the pediatric clinic of Yale-New Haven Hospital with the chief complaint of periumbilical pain not related to eating. However physical examination demonstrated normal findings. Laboratory data including complete blood count, electrolytes, serum proteins, carotene levels, sweat tests and radiologic examinations of the gastrointestinal tract gave normal or negative results.

In the three days before the present admission abdominal pain had become almost constant. The mother noted, that recently the child was lethargic and appeared to have lost weight. A week prior to admission he began to vomit after meals and would only take fluids. The child lay constantly with his legs up, in order to relieve his pain.

No history of diarrhea, jaundice, itching, night sweats or fever was obtained. Past medical history was remarkable for several episodes of bronchopneumonia (ages of 1-2) and several episodes of asthma at age 5 which required epinephrine.

Physical examination at the time of admission showed a white male in moderate distress, lethargic but cooperative. There was a non-tender mass in the right lower quadrant of the abdomen which appeared to be composed of several discrete round lesions. No peripheral lymph nodes were palpable. Laboratory data revealed white blood count 10,400 with a normal differential, hemoglobin 8.4, hematocrit 28.3, sedimentation rate 41; Guaiac test of stools showed occult blood. Barium enema at this time revealed a colocolic intussusception which reduced spontaneously with the enema, and a large lobulated mass in the ileocecal area.(Figure 1)

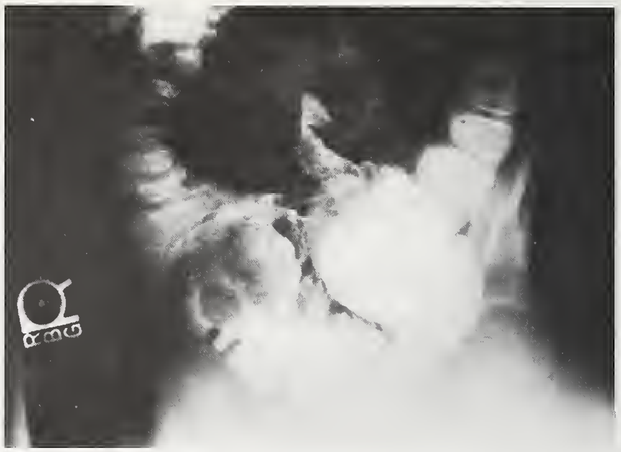

Figure 1
This radiograph shows the large ileocecal mass, noted in Case 3.

Diagnostic impressions at this time included anemia probably due to gastrointestinal blood loss and regional enteritis; one observer suggested the possibility of an intestinal lymphoma.

At surgery, a mass in the cecal area was identified and an ileocolectomy was performed. The surgical specimen consisted of a 10 cm portion of cecum, ileum and appendix. The mesentery showed several enlarged lymph nodes. Upon opening the specimen, a large polypoid mass measuring 6 x 5 x 3 cm was noted projecting into the cecal mucosa. (Figure 2) Cut section showed a fish-flesh appearance. Histologically the tumor was classified as diffuse poorly differentiated malignant lymphoma (Rappaport).[5] (Figure 3) It occupied all layers of the bowel wall, but did not involve serosa. The mesenteric lymph nodes were uninvolved; histologically they showed marked sinusoidal edema and follicular hyperplasia. In addition, sections of ileum proximal to the lesion showed prominent Peyer's patches.

Further evaluation including liver biopsy, bilateral bone marrow biopsies, liver and spleen scans showed no tumor. The patient was staged as I extranodal.

Radiation therapy, 2500 rads, to the abdomen was given. No evidence of disease is noted two years after diagnosis.

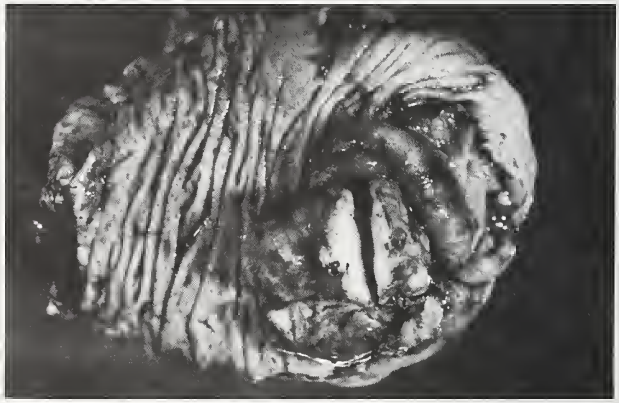

Figure 2
The gross appearance of the tumor in Case 3 is illustrated. Note polypoid configuration.

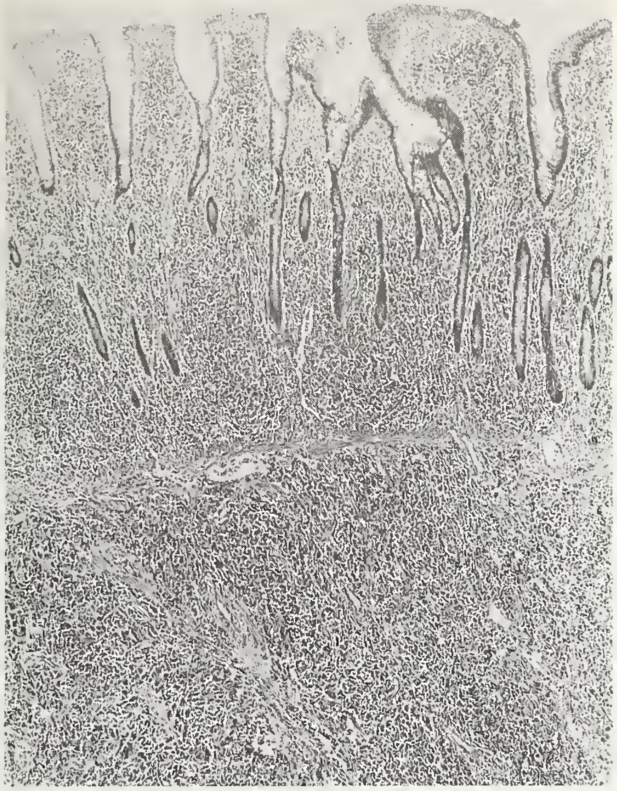

Figure 3
Low power view shows diffuse infiltration of small intestine by lymphoma. Note relative sparing of epithelial crypts and expansion of lamina propria producing villous flattening. (Case 3, H & E, X100).

### Case 4

S.C. was a 2-year-old white male who presented with intermittent abdominal pain and diarrhea of ten months' duration. His pediatrician had diagnosed Crohn's disease; the child was begun on Azulfidine with temporary good clinical results.

A few months later he presented again with diarrhea, abdominal pain, fever, and the presence of a right low quadrant mass. Clinical impression at this time was acute appendicitis with possible abscess formation. He was admitted to Yale-New Haven Hospital for surgery. At the time of operation, the cecum appeared fiable and necrotic; an ileocolostomy was performed.

Pathologic examination of the partial colectomy disclosed massive transmural necrosis. Marked serositis was observed. A few small hyperchromatic cells interpreted as lymphocytes were present in the bowel wall. Despite extensive evaluation of the specimen, no etiology for the necrosis was found.

After discharge, the child did well for a month until purulent drainage developed at the ileostomy site. White blood count at the time was 16,900, hemoglobin 31.8. Antibiotics were administered; the drainage stopped and he was discharged.

One month later, he developed a right flank mass. The clinical impression at the time was that the child had developed an abscess in the psoas muscle.

At exploratory laparotomy, a biopsy of the abdominal wall showed necrotic tissue. Intraabdominal abscesses and adhesions were found and areas suggestive of fistulous tracts were noted. A portion of ileum was resected and an ileotransverse colostomy was performed. Histologically the resected bowel showed preservation of the mucosa with marked edema of the submucosa. Diffuse infiltration of the bowel thickens by what were interpreted as lymphocytes was seen. This was very prominent in the serosa.

Post-operatively, the child developed edema, hypoalbuminemia (2.0 gms/dl) and septicemia. Blood cultures grew E. Coli, streptococcus, staphylococcus, Clostridium and Bacteroides.

Despite aggressive therapy including hyperalimentation, the child deteriorated and died.

Autopsy disclosed a 20 x 20 x 5 cm white7 mass filling the entire retroperitoneum and encasing the sigmoid colon, segments of remaining small and large bowel, mesenteric nodes, ureters, kidneys, inferior right lobe of liver, and gall bladder. Axillary lymph nodes metastases were identified.

Histologically, the mass was composed of small dark hyperchromatic cells. The presence of occasional rosettes led to a diagnosis of neuroblastoma which was confirmed by electron microscopy.

### Discussion

Small cell tumors such as neuroblastoma, embryonal rhabdomyosarcoma, Wihm's tumor and Ewing's sarcoma are common lesions of childhood.[1] Most of these neoplasms occur in specific recognizable primary sites, which area will be easily identified even though metastases have already occurred. Presentation of such a neoplasm as a primary bowel disease is distinctly unusual however. When such a situation does arise, the tumor is far advanced and the prognosis is poor. Our case 4 illustrates this problem.

Our three other patients had small intestinal lymphoma, a tumor not common in childhood.

Among these lymphomas which arise in or affect extranodal tissues, the gastrointestinal lymphoma deserves special attention. Some authors claim that in the small intestine, lymphoma comprises the most common malignant neoplasm;[6] others, that it makes up 1/6 to 1/3 of small bowel tumors.[7-9] However, these lesions are rare; in 1969, Saltzstein reviewed the literature and found fewer than 200 documented primary malignant small bowel lymphomas.[6] These tumors are most commonly seen in older patients in the fourth to fifth decade of life.[7-12]

In children however, intestinal lymphoma represents about 5% of childhood tumors and one-third of all primary malignancies of the small bowel.[1] [13] Dehner claims lymphoma accounts for the most common gastrointestinal malignancy in the pediatric age group.[1]

The frequency of this type of lymphoma in the younger age is well recognized in certain ethnic groups.[14-23] The disease occurs commonly among Iranians, Arabs and Jews of Semitic stock and other middle eastern populations. In these groups, it constitutes up to 96.9% of all small intestinal neoplasms. Lymphomas in these patients tend to occur in the upper small bowel, may be associated with immunoglobulin (IgA) abnormalities, show lymphoid or lymphoplasmacytic hyperplasia in nontumorous bowel and often are associated with malabsorption.[14-22] Although common in young adults, even Mediterranean lymphoma is rare in the pediatric age group.

It is generally agreed that symptoms of chronic or acute intestinal obstruction are the most frequent clinical findings produced by small bowel lymphoma; these include abdominal pain, nausea, vomiting, anorexia and weight loss.[9-12] Malignant lymphoma is associated with a high incidence of intussusception.[4 6 9] Intussusception was present in our cases. It is suggested that this is caused by the polypoid characteristics of the tumors.

Fever, sweats and chills are manifestations in cases of malignant lymphomas in both children and adults.[4 6 9 12] However, in small bowel lymphomas, these are not seen until late in the disease, and never as initial complaints.

The recommended treatment of choice for bowel lymphoma in children includes surgical resection with removal of regional nodes.[4 6 9 22] Radiation and chemotherapy may be added in those cases in which regional nodes or distant sites of involvement are recognized, i.e., for high stage disease.[4 9 13 21 22]

Chemotherapy for pediatric small bowel lymphoma has been directed along similar lines as for node-based childhood lymphoma.[13] To our knowledge, series of small bowel childhood lymphoma evaluating therapeutic modalities have not been published.

Rarely, the onset of symptoms may be dramatically produced by perforation of the tumor and diffuse peritonitis.[9] Peripheral lymphadenopathy and hepatomegaly are uncommon findings. The presence of hepatic enlargement at initial evaluation indicates advanced disease. Enlarged mesenteric and paraaortic lymph modes are found in approximately 50% of the cases; however, these lymph nodes may not be involved by neoplasm but may represent reactive hyperplasia. Histological involvement of the regional lymph nodes is usually interpreted as a poor prognostic sign.[6 9]

Grossly these tumors can follow several patterns: a polypoid mass (the most common pattern in children), discrete ulcers, or diffusely infiltrating annular lesions have been reported.[4 6 9 22] The terminal ileum and cecum are the sites most commonly involved, accounting for 85 to 90% of these tumors.[4 6 9]

The clinical diagnosis of malignant lymphoma in children may present difficulty. Inflammatory bowel disease especially Crohn's disease and acute appendicitis are the conditions most frequently considered since they share common symptomatology. Even the presence of a mass lesion may not be helpful since intramural and extramural abscesses may occur in Crohn's disease and appendicitis. In this study, one patient erroneously diagnosed as regional enteritis was treated for several months with steroids. This error illustrates the necessity of biopsy for diagnosis in such cases.

Pathologically, the distinction between Crohn's disease and lymphoma is made easily. The differentiation of lymphoma from other small tumors, such as neuroblastoma, may be difficult (Case 4) . Degree of differentiation, sample size, extent of tumor necrosis, and unusual location of such tumors may lead to erroneous diagnosis.[1] Careful histopathologic evaluation and the use of ultrastructural or tissue culture studies may be necessary for this distinction.

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# “Real Time” Ultrasonic Evaluation of the Breast

## JEFFREY S. BLAU, M.D. AND JULIAN MANDELL, M.D.

**ABSTRACT—“Real Time” Ultrasound (ultrasound fluoroscopy), using no radiation, can be very helpful in rapidly differentiating hard to diagnose mammary cysts from solid lesions. It is still difficult to accurately differentiate benign solid from malignant solid tumors with a benign growth pattern. Scirrhous malignancies have a characteristic ultrasonic pattern.**

“Real Time” ultrasound (ultrasound fluoroscopy) evaluation of the breast is similar to the ultrasonic evaluation of other superficial anatomic structures. The breast is compressible, and allows the use of high frequency transducers which give the highest resolution images. The development of high frequency transducers in the range of 5.0 to 7.0 MHz has enabled the ultrasonographer to obtain high resolution imaging of breast and thyroid tissue. In this study a 7.0 MHz “real time” ADR unit was used for its speed and accuracy when compared to a standard “B” scanner.

“Real Time” ultrasonography of the breast is a simple, safe, and accurate method to evaluate the solid or cystic nature of a mass found either by palpation or mammography. Patients with cystic masses can usually be aspirated in a doctor’s office on the same day. This alleviates much financial and emotional stress.

According to Kobayashi, there are three main criteria to use in evaluating breast lesions with ultrasound.

(1) Boundary echoes and shape
(2) Internal echoes
(3) Shadowing

The concept of accentuation of posterior echoes leading to a “tadpole” sign, is important in evaluating breast disease. The sign denotes a strong build up of echoes posterior to a cyst wall which are more intense than the surrounding breast stroma echoes. (Figure 1) Ultrasonic images can be recorded on x-ray film or polaroid film.

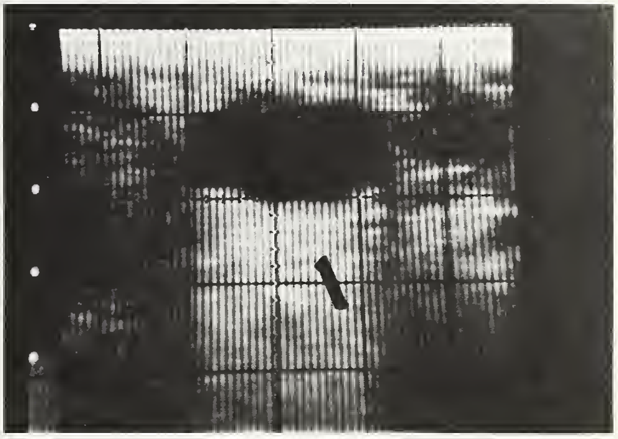

Figure 1
An example of the “Tadpole” sign (see arrow) indicating accentuation of the posterior echoes. Aspiration revealed a cyst.

Most breast masses we see are fluid-filled. Ultrasound allows us to evaluate these masses accurately without using radiation. Mammary cysts which contain homogeneous fluid appear echo-free on ultrasonic scan. The front and back walls appear strongly reflective and visible, while cystic fluid is echo-free. Occasionally a septum is seen within a cyst which will produce a visible linear band. If the gain is increased, there will be a gradual peripheral increase in echoes, but the center of the cyst will remain echo-free. The presence of what Kobayashi calls a “tadpole” sign is the hallmark of a benign cyst. Lateral acoustic shadows (narrow vertical bands containing no echoes) are believed to be caused by refraction of echoes from a lesion with a smooth wall and are seen with benign cysts. (Figure 2)

Benign solid lesions such as fibroadenomas and malignancies with benign growth patterns (colloid and medullary carcinomas), show a relatively homo-

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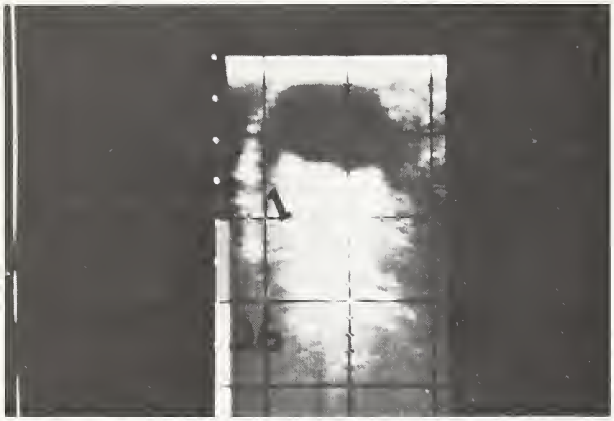

Figure 2
Another example of the "Tadpole" sign as well as lateral acoustic shadowing. (See arrow) Aspiration revealed a cyst.

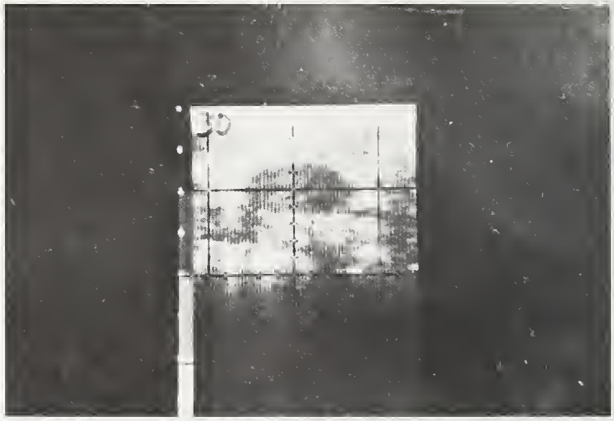

Figure 3B
Benign adenoma (3A) showing low level internal echoes and absence of the "tadpole" sign.

geneous echo pattern. These types of masses attenuate little of the sound energy and may present with sharply defined anterior and posterior walls. If the walls of the lesions are smooth, they may also present with lateral shadows. The most important differentiation between solid benign tumors and benign cysts is the presence of low level echoes within the solid masses and the absence of a "tadpole" sign. Currently, we cannot distinguish between a solid benign tumor and a malignancy with a benign growth pattern. Both may present similar ultrasonic pictures. Figure 3 (adenoma), Figure 4 (medullary carcinoma).

Infiltrating malignancies and non-circumscribed scirrhous carcinomas have a characteristic ultrasonic pattern. These lesions have irregular walls and irregular internal echoes. The absence of posterior echoes is the most characteristic finding seen within infiltrating and scirrhous malignancies. It has been called the acoustic middle shadow by Kobayashi. The patient in Figure 5 has an invasive carcinoma with absence of posterior echoes. Invasive malignancies attenuate the sound energy, which produces the acoustic shadowing beneath or behind the lesion.

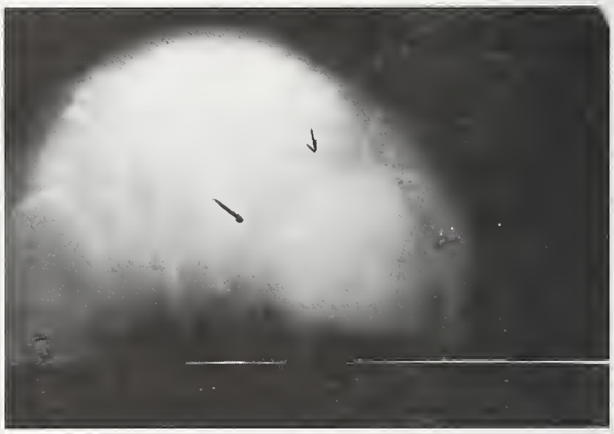

Figure 4A
Large mass in a 29-year-old, ill-defined.

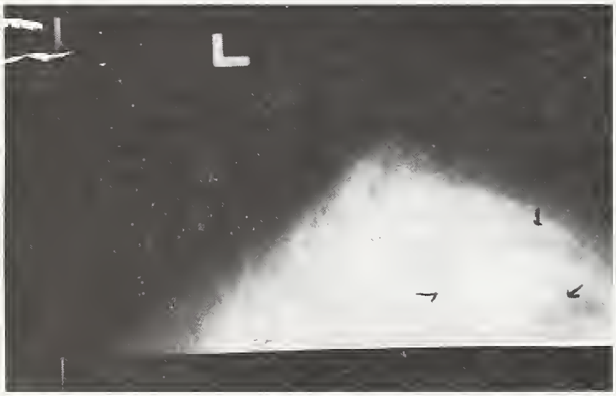

Figure 3A
Mammogram showing an ill-defined mass in the inferior aspect to the breast. Biopsy revealed benign adenoma.

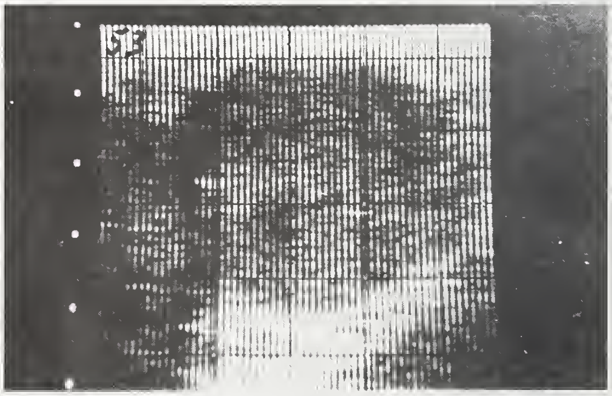

Figure 4B
Ultrasound showing low and high level echoes with posterior transmission of sound. Biopsy revealed medullary carcinoma.

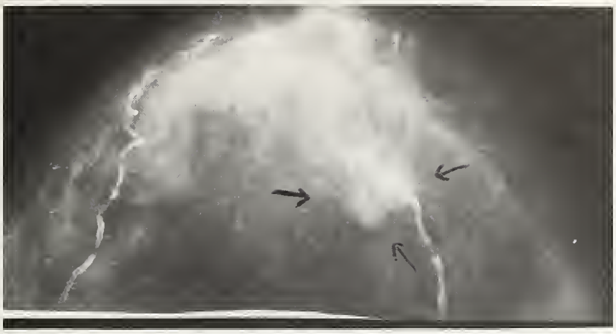

Figure 5A
Mammogram revealing a suspicious lesion.

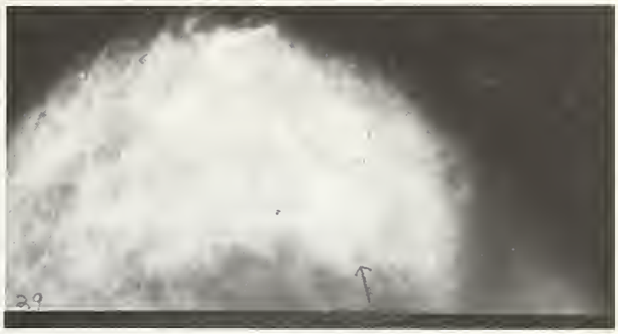

Figure 6A
A mass with a poorly defined posterior border.

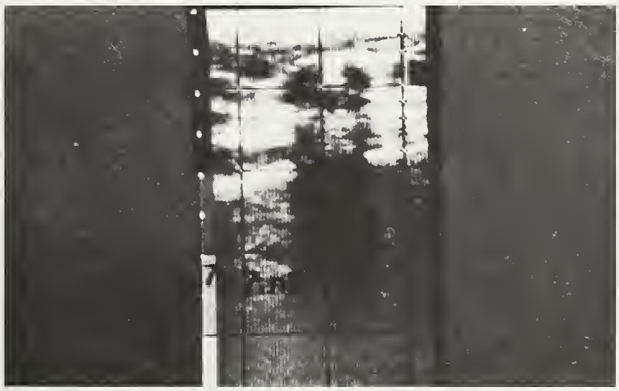

Figure 5B
Scirrhous carcinoma with absence of posterior echoes. This is the acoustic middle shadow sign. Irregular internal echoes are present.

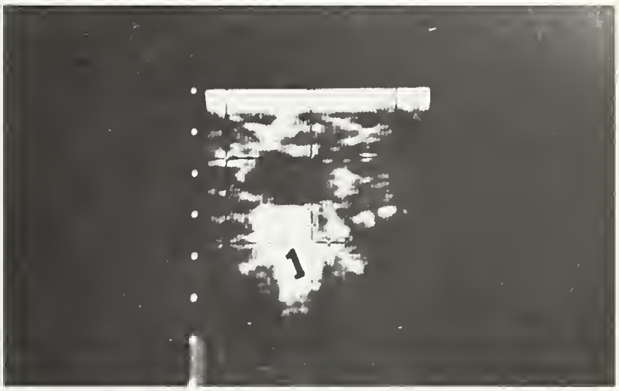

Figure 6B
Ultrasound reveals a "tadpole" sign. Aspiration revealed a benign cyst.

## Conclusion

Ultrasound is indicated with any lesion greater than 1 cm. in size which does not have a characteristic mammographic appearance. If the lesion fulfills the ultrasonic criteria for a cyst, aspiration can be performed, usually on the same day, in the doctor's office. If the lesion is solid, a biopsy should be performed. If the lesion has ultrasonic criteria for malignancy, then the surgeon should schedule the patient accordingly.

Work is being done by Kobayashi, Baum and Jellins and others in hope of replacing mammography with ultrasound. Presently, we should consider ultrasound and mammography as complementary studies. Ultrasound, using no radiation, can increase the accuracy of mammography, especially with cystic and invasive lesions. Ultrasound has been exceptionally helpful with cystic lesions that look benign on mammography except for an ill-defined posterior wall. It is not uncommon for cysts to be obscured by dense fibrous stroma and the use of ultrasound greatly increases the accuracy of diagnosis. (Figure 6) Benign solid lesions and those malignancies with a benign growth pattern still cannot be differentiated with a high degree of accuracy. According to Teixidor and Kazam, the combined evaluation of breast masses by mammography and sonography gives a higher accuracy rate than either method alone. "Real Time" ultrasound offers more convenience, speed and accuracy than conventional scanning.

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## A CASE OF LIBEL

### Physician Sues Others for Libel in Complaining to Board of Medical Examiners

A trial court erred in enjoining a physician from proceeding with a libel action, the Georgia Supreme Court ruled.

The physician filed a libel action against other physicians and a physician's assistant who allegedly defamed him professionally by complaining to the State Board of Medical Examiners. He also named reporters and publishers of a newspaper, alleging defamation in newspaper articles.

The physicians named in the libel action sought to enjoin it because the physician had obtained the complaints and a complete copy of the investigative file from a secretary employed by the Board. His attorney has used it to prepare the action before the state law department requested its return.

The trial court entered an injunction restraining the physician from proceeding in the libel action because of his use of copies of his file in preparation of the case. On appeal, the Georgia Supreme Court did not agree that the suit should be enjoined. The court said that even if the physician's conduct with regard to the investigative file was felonious, unethical, reprehensible, and without good conscience, such acts alone did not deprive him of the right to sue for libel.

The Supreme Court said that because of the ruling that the Board's file was absolutely confidential, neither the physician nor anyone else would be able to introduce any part of it into evidence. Although the physician might have obtained some advantage because of his recollection of the file contents, the court said, nothing would prevent the parties being sued from discovering the way the physician was seeking to structure and prove his case against them.

The court reversed the trial court's judgment.—*Morton v. Gardner,* 252 S.E. 2d 413 (Ga. Sup. Ct., Jan. 5, 1979; rehearing denied, Jan. 23, 1979).

—*The Citation,* Aug. 15, 1979

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**Brief Summary**

**INDICATIONS:** For the prevention and treatment of nocturnal recumbency leg muscle cramps, including those associated with arthritis, diabetes, varicose veins, thrombophlebitis, arteriosclerosis, and static foot deformities.

**CONTRAINDICATIONS:** Because of the quinine content, Quinamm is contraindicated in women of childbearing potential, in pregnancy, in patients with known quinine sensitivity, and in patients with glucose-6-phosphate dehydrogenase deficiency. Hemolysis (with the potential for hemolytic anemia) has been associated with a G-6-PD deficiency in patients taking quinine.

**PRECAUTIONS:** Thrombocytopenic purpura may follow the administration of quinine in highly sensitive patients. Recovery will follow withdrawal of the medication.
Cinchona alkaloids, including quinine, have the potential to depress the hepatic enzyme system that synthesizes the vitamin K-dependent factors. The resulting hypoprothrombinemic effect may enhance the action of warfarin and other oral anticoagulants.

**ADVERSE REACTIONS:** Aminophylline may produce intestinal cramps in some instances, and quinine may produce symptoms of cinchonism, such as tinnitus, dizziness, and gastrointestinal disturbance. If ringing in the ears, deafness, skin rash, or visual disturbances occur, the drug should be discontinued.

**DOSAGE AND ADMINISTRATION:**
1 tablet upon retiring. When necessary, 1 additional tablet may be taken following the evening meal.

Product Information as of September, 1977

U.S. Patent 2,985,558

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# Chronic Obstructive Lung Disease: An Investigation of Referrals for Patient Education

GODFREY D. RIPLEY, M.D.

**ABSTRACT—The low utilization of a patient education program for chronic obstructive lung disease (COLD) is investigated. Whilst focused specifically on the zero referral rate from a family medicine teaching practice, it is suggested that this speciality is not alone in giving this treatment modality the cold shoulder.**

### Introduction

COLD is the somewhat symbolic acronym for chronic obstructive lung disease-the result primarily of chronic bronchitis and emphysema, with bronchiectasis, asthma and pneumoconiosis playing less frequent causative roles. Patient education programs have a recognized place in the medical management of this disabling disease and this paper presents an investigation into the provision of such a treatment facility within a community and of the referral rate to the program from physicians in a family medicine teaching practice.

### Etiology

The disorder is characterized by widespread narrowing of the bronchial airways especially on expiration, causing abnormal resistance and consequent obstruction to the flow of oxygen into the lungs. It is significant that the first published descriptions of these diseases occurred following the impact of the Industrial Revolution in England. The word emphysema was first recorded in a paper published in London in 1793[1] with chronic bronchitis following closely in 1808.[2] Today, genetic predisposition, infection, allergy, emotional stress, environmental pollution and tobacco are all recognized as playing a part in the causation and development of COLD.

### Presentation and Progress

The disease may be unsymptomatic and undetected for varying periods of time but in due course will produce both symptoms and disability as the result of restriction in oxygen intake. "Wheezing", "Tightness in the chest" and "Shortness of breath"—both paroxysmal and persistent—are the common hallmarks of the condition which, when untreated, is uniformly progressive. As the disease becomes established with irreversible pathological lung changes, disability becomes greater, influencing and restricting the patient's activities of daily living (ADL) and leaving him a respiratory cripple. In due course repeated infections to which he now has a progressively lowered resistance compound the disturbance to his vital functions, and death eventually ensues from respiratory failure.

### Epidemiology

Twenty percent of the adult male population of the United States has some clinical degree of the disorder with documented respiratory disability.[3] [4] It was estimated that during the year 1967 the cost of COLD in morbidity and mortality was $1.8 billion, with 90,000 man/years lost from work.[5] As our nation entered the 1970's, it was reported that about 15,000 middle-aged Americans were becoming disabled each year as result of COLD and that its death toll together with that of its consequences was at least 100,000 annually.[6] [7]

The prevalence of COLD in 1977 in Connecticut was estimated at 245,000 of whom two-thirds have their ADL restricted to an appreciable and significant degree.[8] [9]

### Treatment

Drugs, breathing exercises, counseling and patient education are included in the treatment plans recommended by contemporary authorities[3] [10] [11] who claim that appropriate educational programs for patients will contribute to improved exercise toler-

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ance and lung function, decreased exacerbations of illness, depression and anxiety and will reduce premature deaths by decreasing the episodes of acute respiratory failure.

"Physicians are coming to realize the necessity for bringing about lifestyle changes in patients to reduce illness and disability."[12]

"The physician needs to educate the patient and his family about his condition or use available community resources to aid in this endeavour."[13]

### The Investigation

To what extent are physicians responding to such comments? Are patient education programs, where available, included in the treatment plans of the primary care physician, now playing in increasing role in the continuing care and management-disease in the community? Specifically, do physicians in a family medicine training practice, a component of a university school of medicine, refer their patients with COLD for group educational programs?

### Method

The family medicine office investigated has a practice population of approximately 5,500. Presentations by patients with COLD during the first six months of 1978 were identified by means of a computerized record, charts being perused visually with regards the recorded content of the physicians' treatment plan. The conurbation within which the practice is situated has a population of approximatley 250,000.[14] Extrapolation from the 1970 National Health Survey[8] demonstrates that approximately 20,000 of these are afflicted with COLD and of these perhaps 14,000 have a significant reduction in their ADL.[8] [9] The conurbation contains the Head Office of the State Lung Association which actively offers patient education programs for COLD sufferers based on an 8-week group training cycle at no charge to the participants. Investigation of the census of the program was undertaken together with enquiring into the possibilities for expansion.

### Results

*A. The Treatment*

Thirty participants were identified as attending the Lung Association's patient education program which is held twice yearly. The Association states that additional programs will be conducted when the demand manifests itself, there being no present shortage of trained personnel nor of funds.

*B. The Prescription*

Twenty-five patient-encounters were identified with the diagnosis of COLD during the period under review. In none of these charts could referral to a patient-education group be found as part of the physician's treatment plan. It must be conceded that the absence of such written comment does not of itself show its absence from the physician's management of the patient—only that it was not recorded.

### Conclusions

This investigation should not be seen as singling out Family Medicine as falling below generally accepted standards of medical care. Bearing in mind that only one in 700 of the target group was attending the educational program, the suggestion is that physicians in all relevant specialities have been unable either to perceive the potential of this treatment or to influence their patients to participate.

"Patients' needs should ideally be the concern of their (physician) who can at least open the way to other sources of help."[15] The manifest discrepancy between this expectation and reality demands investigation and further studies are underway. Areas to be addressed include informational strategies from the Lung Association to physicians, referral rates from other specialities and program outcomes. The question to be faced however is not so much that posed by a patient-education program dealing with a chronic respiratory disease. Rather is is whether physicians can be influenced to regard in a more positive way treatment models provided by community-based agencies and to discontinue their cold shoulder treatment for therapy not given under their immediate supervision.

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# Clue to the Diagnosis of Aortic Dissection

MARTIN JEFFREY FRANK, M.D., DAVID BALDWIN, M.D.
AND NATHAN FRANK, M.D.

**ABSTRACT—A patient with aortic dissection into the pericardium is described. The clue to the diagnosis was ST segment elevation on the electrocardiogram.**

Dissection of the aorta is often a problem in diagnosis because of its varied presentation. Obviously, such a potentially catastrophic illness must be recognized as soon as possible to initiate appropriate therapy. Thus any clinical clue may be of vital importance. Although the electrocardiogram is generally felt to be non-specific, it may be a valuable sign of dissection into the pericardium as illustrated in the case below.

An 83 year-old white man was admitted to the Middlesex Memorial Hospital in December 1977 because of chest pain and shock. For approximately 3-4 hours prior to admission, he complained of severe "pressure-like" substernal discomfort with associated nausea and diaphoresis. On admission to the hospital, blood pressure was unobtainable. Swan-Ganz catheter readings showed low-normal pressures (mm. Hg) as follows: pulmonary artery: 14/6, and pulmonary capillary wedge: 5. The patient initially responded well to volume replacement with normal saline.

Physical examination revealed an elderly man, cyanotic, in moderately-severe distress from chest pain. The vital signs were a pulse of 72, respirations-20, blood pressure of 120/80 (after saline) without pulsus paradoxicus, and a temperature of 98.6 F. The jugular venous pressure at 45 degrees elevation was normal. There were scattered crepitant rales at the lung bases. There was a left ventricular heave on cardiovascular examination. The heart sounds were distant. There was an S4 but no S3, pericardial friction rub, or diastolic murmur. Carotid, brachial, radial, and femoral pulses were all palpable and equal, without any bruits. No pulses were appreciated below the femorals. The abdomen was not tender and there was no organomegaly. The extremities were warm without any clubbing or edema. Neurological examination was normal.

Past history was sketchy, but he was aware of hypertension and gout for several years. He was not taking any medication.

The initial electrocardiogram showed non-specific ST-T changes in the precordial leads with minimal ST elevation in leads V1-3 and a biphasic T wave in V6 (see Figure 1). Chest X-ray was unremarkable except for borderline cardiomegaly and minimal widening of the ascending aorta.

The differential diagnosis was as follows: 1) Myocardial infarction with hypovolemia, 2) Pulmonary embolus, and 3) Aortic dissection with pericardial tamponnade.

During the four days of hospitalization, there was no elctrocardiographic or enzymatic evidence for a transmural myocardial infarction. A standard perfusion lung scan was normal. An echocardiogram showed an echo-free space anterior to the right ventricle. Because there was no other evidence for pericardial tamponnade, this recording was felt to be spurious for the diagnosis of pericardial effusion.

The patient continued to have recurrent chest pain. His blood pressure was maintained by normal saline. On the last two hospital days, the electrocardiogram showed new significant ST elevation in the precordial leads, especially in V3-4, compatible with an injury current (see Figure 1). No Q waves indicative of transmural myocardial infarction were present.

On the fourth hospital day, the patient had sudden massive hemoptysis and expired. Post-mortem examination revealed a dissecting aneurysm of the aortic arch with retrograde dissection into the pericardium and anterograde dissection into the mediastinum. The pericardium was filled with blood as were both pleural cavities. There was extensive hemorrhage into the mediastinal fat and into the hila of both lungs.

The purpose of this report is to emphasize the importance of ST segment elevation as an indication of dissection into the pericardium. This finding reflects the epicardial injury current produced by the blood in the pericardial cavity; it is analagous to any other pericarditis.

One of us (N.F.) has noted these electrocardiographic changes in three other patients not previously reported. In 1950, Levinson et al.[1] reported an incidence of a "pericarditis" pattern in approximately 10% of patients with dissection.

Somehow current literature has not stressed this finding. In a standard cardiology textbook, Lindsay[2] mentions the electrocardiogram as being non-

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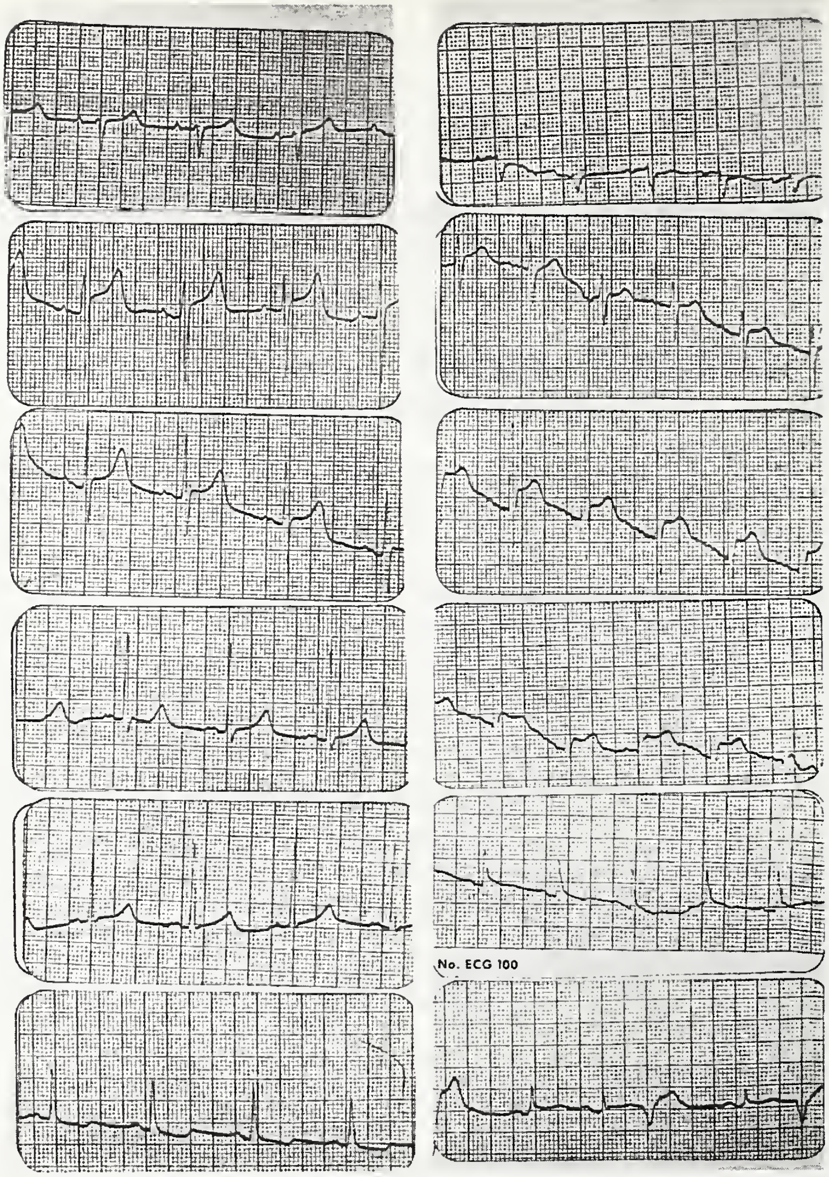

Figure 1

A. Initial ECG with leads V1-6 from top to bottom. There is minimal ST segment elevation in V1-3 and a biphasic T wave in V6. B. ECG on the third hospital day, again with leads V1-6 ST segment elevation is present in V2-6, especially in V3-4. PVC's are present in V6.

specific. Slater and DeSanctis[3] in their excellent review of this subject, state that the electrocardiogram can be helpful diagnostically in a "negative sense, " i.e. absence of myocardial infarction by ECG in a patient whose history is compatible with it, may indicate dissection. Indeed, this was true in our patient. To add to this point, ST segment elevation without infarction, in a hypotensive critically-ill patient with chest pain, suggests aortic dissection into the pericardium.

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# Treatment of Uterine Cancer at Small Institutions

## DANA EDWARD JOCK, M.D.

**ABSTRACT—An attempt has been made to analyze data pertaining to the treatment of uterine cancer at a small, non-cancer specialized institution, The Mary Imogene Bassett Hospital in Cooperstown, New York. Other such smaller centers have been urged to do the same, hopefully to stimulate discussion from authorities in the field of cancer research and treatment addressing this issue. Adjusted Five-Year Survival Rates indicate 89% Stage 1 epidermoid carcinoma of the cervix and 93% Stage 1 adenocarcinoma of the endometrium were alive and free of disease. The study included 115 epidermoid carcinoma of the cervix and 132 adenocarcinoma of the endometrium. Treatment modalities and physician follow-up remained relatively constant over the 25 year study period. Serious complications included a fistula rate of 11.3% of those treated for epidermoid carcinoma of the cervix, rectovaginal fistulae predominating (8/13). These were carefully scrutinized, and point to the need for improved radiotherapeutic technique.**

Should cancer be treated at small institutions or should every effort be made to channel the care of cancer patients into the centers specifically designated? In good conscience, it behooves every smaller center to periodically assess its Five-Year- Survival rate and ask itself if it is keeping abreast of current concepts of cancer therapy. The late Dr. Richard H. Andresen felt that cancer in our area should primarily be treated at major cancer centers. This study was undertaken solely for the purpose of deciding if we could, in good faith, continue to recommend cancer treatment at our institution. We think we can.

### Case Material

The population is rural in nature and includes Otsego, Madison, Herkimer, Oneida, Delaware, Albany, Schoharie, Fulton, and Sullivan Counties in Upstate New York. Our average age for carcinoma in situ of the cervix (43), epidermoid carcinoma of the cervix (54), and adenocarcinoma of the endometrium (61) reflects an older population base than nationally for these malignancies (35-38, 45-48, and 54-58 respectively). From 1950-1970, for instance, Otsego County claimed 14% of its female population over the age of 65 compared to 10% for the rest of the United States.

One failure in reaching this cancer population is brought to light by the fact that, although 90% of our patients with adenocarcinoma of the endometrium experienced obvious bleeding abnormalities, 20% of these patients waited over 2 years before seeking medical attention. This may point to a need for an advertising campaign, either locally or nationally, such as those promoting PAP tests and self breast exams. A full 80% of the 90% of patients with adenocarcinoma of the endometrium who presented with abnormal bleeding had post-menopausal bleeding, again pointing to that age group with which we are dealing.

Table 1

| | *Carcinoma In Situ Cervix* | *Carcinoma Cervix* | *Carcinoma Endometrium* |
|---|---|---|---|
| Number of Cases | 69 | 115 | 132 |
| Average Number of Pregnancies | 3.3 | 3.0 | 2.0 |
| Chief Complaint: | | | |
| None (Abnormal Pap) | 46/69 | 13/115 | 2/132 |
| Post Menopausal Bleeding | 2/69 | 45/115 | 91/132 |
| Other Abnormal Vaginal Bleeding | 13/69 | 32/115 | 25/132 |
| Vaginal Discharge | 6/69 | 13/115 | 2/132 |
| Constitutional Symptoms | 1/69 | 6/115 | 6/132 |
| Pelvic, Back, or Abdominal Pain | 1/69 | 6/115 | 6/132 |
| | 69/69 | 115/115 | 132/132 |

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Patients treated for uterine cancer from 1950-1974 at the Mary Imogene Bassett Hospital in Cooperstown, New York.

Reprint requests to: 75 Magnolia Road, Trumbull, CT 06611 (Dr. Jock).

Table 2

| | *Carcinoma In Situ Cervix* | *Carcinoma Cervix* | *Carcinoma Endometrium* |
|---|---|---|---|
| Method of Initial Diagnosis: (Confirmed by Biopsy) | | | |
| Pap Smear | 54/69 | 23/115 | 5/132 |
| Biopsy | 11/69 | 88/115 | 57/132 |
| D&C | 0/69 | 0/115 | 64/132 |
| Unsuspected at Surgery | 3/69 | 1/115 | 3/132 |
| Autopsy | 1/69 | 3/115 | 3/132 |
| | 69/69 | 115/115 | 132/132 |
| Lost to Follow-up | 5/69 | 1/115 | 6/132 |
| Average Age at Diagnosis | 43 | 54 | 61 |
| (National Average) | (35-38) | (45-48) | (54-58) |
| Median Age | 41 | 53 | 62 |
| Average Duration of Chief Complaint | 23 weeks | 27 weeks | 64 weeks |

Carcinoma statistics for 1950-1974 at the Mary Imogene Bassett Hospital.

There were 69 patients with carcinoma in situ of the cervix, 115 epidermoid (squamous) carcinomas of the cervix, and 132 adenocarcinomas (including adenoacanthoma) of the endometrium treated from 1950-1974. Over the same treatment period there were 5 adenocarcinomas of the cervix (4% of cervix cancers), 3 adenosquamous carcinomas of the endometrium, 5 mixed mesodermal tumors (carcinosarcomas), and 4 sarcomas of the uterus.

Kottmeier[1] reports a 6% incidence of multiple primary malignancies involving other organ systems in his 10 year follow-up of carcinoma of the cervix. More recently Mould and Barrett[2] have reviewed most large series and have demonstrated between 2-4% development of new primaries. Their own study reports a new primary malignancy rate of 2.6% after the diagnosis of carcinoma of the cervix (mean age cervix cancer 52.6 years), excluding skin cancers. Our own experience indicates 8.7% of carcinoma in situ patients, 11% of those with invasive carcinoma of the cervix, and 17% endometrial cancer victims harbor or develop a second, or even third, primary malignancy. These higher figures than usually reported include skin cancers, and also seem to reflect the mean age populations involved.

## Diagnostic Techniques

Cone biopsy was the primary diagnostic tool in evaluating carcinoma in situ and invasive carcinoma of the cervix during this study period. Since 1974, however, colposcopy directed biopsy and follow-up has assumed the primary role.

At this institution out-patient endometrial biopsy was used as the chief mode of diagnosis of endometrial carcinoma (43% of the 132 cases); formal inpatient D&C was reserved for cervical stenosis patients and as the diagnostic tool utilized by outside referring physicians. This procedure resulted in only one major complication, hemorrhage requiring admission and transfusion, and a known failure in detection rate of 6.4% (4/61 required D&C for definitive diagnosis). An *apparent* 93.6% accuracy of endometrial biopsy exists. However, in spite of our relatively stable rural population with generally good follow-up, there is potentially a large "unknown" of those lost to follow-up after out-patient biopsy from moving, death from other causes, etc. This makes accuracy of endometrial biopsy difficult to evaluate, but that is not the purpose of this study.

## Radiotherapy Techniques

Primary radiotherapy for carcinoma of the cervix involved mainly intracavitary radium (either Manchester Technique with ovoids and tandem or Ernst applicator) combined with external whole pelvis Cobalt 60, the order of the two being determined by such factors as bulk of the lesion, type of lesion, and the availability of the endocervical canal for insertion. External radiotherapy following surgery was usually reserved for recurrence or clinically understaged lesions discovered at the time of surgery.

Radiotherapy for endometrial carcinoma consisted essentially of intracavitary radium (via Heyman Capsules or Ernst applicator) prior to surgery for bulkier lesions (endometrial cavity greater than 8 cm.) or external irradiation (Cobalt 60) post-operatively for more deeply invading lesions or lesions understaged clinically.

## Treatment Results

A joint approach by the gynecologist and the radiotherapist has yielded an over-all Five-Year Survival (Stages 1-4) of 57% for invasive carcinoma of the cervix and 77% for adenocarcinoma of the endometrium, including deaths from all causes and all patients lost to follow-up. Stage 1 of the cervix has 81% Five-Year Survivors (30/37) and Stage 2 claims 56% (18/32) Survivors. There are 80% Stage 1 surviving five years with endometrial carcinoma. Adjusted Five-Year Survival Rates for all stages combined include 63% for cervix and 80% for endometrial cancers. Adjusted Five-Year Survival Rates for Stage 1 of the cervix was 89% and Stage 1 of the endometrium was 93%. Adjusted rates were computed by applying the percentage of known and presumed cancer deaths in our series to those lost to follow-up and to those known to have died from intercurrent illness. This gives an estimation of cancer deaths for the whole group.

Cone biopsy followed by vaginal or abdominal hysterectomy was primary treatment for carcinoma in situ of the cervix. For invasive carcinoma of the cervix 72% received radiotherapy alone, 24% surgery alone, and 4% combined irradiation and surgery. Adenocarcinoma of the endometrium was treated by surgery alone in 43% (57/132 patients), irradiation alone in 15% (20/132), and combined surgery and radiotherapy in 38% (50/132). Five patients were not treated.

Table 3

FIVE-YEAR SURVIVAL COMPARISON STATISTICS,[3] IN PERCENTAGE, CANCER OF CERVIX

| | *Univ. of Tenn. 1950s* | *Stockholm Heyman 1940s* | *Stockholm Kottmeier 1950s* | *M.D. Anderson ortho-voltage 1950s* | *M.D. Anderson supervoltage 1950s, 1960s* | **Mary Imogene Bassett Hospital 1950s, 1960s* |
|---|---|---|---|---|---|---|
| Stage 0 | | | | | | 100 |
| Stage 1 | 68 | 78 | 89 | 90 | 94 | 81 (30/37) |
| Stage 2 | 38 | 44 | 53 | 70 | 79 | 56 (18/32) |
| Stage 3 | 22 | 28 | 34 | 37 | 47 | 25 (5/21) |
| Stage 4 | 2½ | 4 | 8 | 5 | 16 | — (1/5) |
| All Stages | 38 | | 50½ | 59 | 64 | ** 57 |

*Mary Imogene Bassett Hospital Five-Year Survivals include death due to all causes and one patient lost to follow-up (Stage 2).

**Not included are the 20 patients (115 total) from 1972-1974 (less than 5 years lapse.)

[3] Table extracted in its entirety from *Synopsis of Gynecologic Oncology;* Philip J. Disaia, C. Paul Morrow, Duane E. Townsend; John Wiley and Sons, New York; 1975, P. 40.

Table 4

FIVE-YEAR SURVIVAL COMPARISON STATISTICS,[3] IN PERCENTAGE, CANCER OF ENDOMETRIUM.

| | *Combined Series* | *Bassett Hospital** |
|---|---|---|
| Stage 1 | 76.2% | 82% (75/91) |
| Stage 2 | 51% | — (3/7) |
| Stage 3 | 25.6% | — (5/10) |
| Stage 4 | 8.8% | — (0/10) |
| All Stages | 68.3% | 70% |

[3] Table extracted from *Synopsis of Gynecologic Oncology,* Philip J. Disaia, C. Paul Morrow, Duane E. Townsend, New York, John Wiley and Sons, 1975, P. 130

*Bassett Hospital Five-Year Survivals include death due to all causes and six patients lost to follow-up. Not included are the 14 patients (132 total cases endometrial cancer) treated 1972-1974, since 5 years has not elapsed since treatment.

Table 5

ADJUSTED* FIVE-YEAR SURVIVAL RATES FOR BASSETT HOSPITAL 1950-1974, IN PERCENTAGE.

| | *Epidermoid Carcinoma Cervix* | *Adenocarcinoma Endometrium* |
|---|---|---|
| Stage 0 | 100 | — |
| Stage 1 | 89 (33/37) | 93 (86/92) |
| Stage 2 | 66 (21/32) | — (4/7) |
| Stage 3 | 25 (5/21) | — (6/10) |
| Stage 4 | — (1/5) | — (0/10) |
| All Stages | 63 (60/95) | 80 (96/119) |

*Adjusted rates were calculated by applying the death rate of known and presumed cancer deaths to those lost to follow up and to those dead of intercurrent illness and adding those to the known and presumed cancer dead.

## Complications

There occurred 12% major complications (14 out of 121 procedures) in the diagnosis and treatment of carcinoma in situ of the cervix (including 5 hemorrhages, 4 abscesses, 1 urinary tract injury, 1 thrombophlebitis, 2 pulmonary emboli, and 1 ileus).

Of all patients treated for carcinoma of the cervix 26% developed major complications (including those listed above plus fistulae in 11.3%). Multiple complications arose in 22% of those treated, indicating that complications tend to compound themselves.

Treatment of adenocarcinoma of the endometrium tended to be frought with fewer major problems, occurring in only 7% of those treated, in spite of the older age group and associated medical problems.

In reviewing the list of complications the 11.3% fistula rate was at first quite disturbing. Most series report between 1% and 4% fistula formation following therapy. Boronow and Rutledge[4] report a 1.2% vesicovaginal fistula rate following radiotherapy and commented on the fourfold increase when hysterectomy and radiotherapy were combined. Buchler et al.[5] focused on immediate intestinal radiation reactions and correlated the severity of those reactions with the seriousness of late reactions including bowel obstruction, perforation, and fistulae. Kottmeier[6] writes of a 0.2% mortality rate with radiotherapy and a fistula rate of approximately 2%, excluding however, immediate post-operative fistulae and terminal fistulae associated with recurrent cancer. Adding those two groups indeed brings the total fistula rate to 10.5%. Currie[7] reports a fistula rate of 1.9% in patients selected for radical surgery, all of which were ureterovaginal or vesicovaginal fistulae. Finally Strockbine, Hancock, and Fletcher[8] from M.D. Anderson suggest a 3.9% fistula rate arising from therapy, although one cannot be sure whether or not this includes the 50/50 ratio of rectovaginal to vesicovaginal fistulae they speak of, or if, in actuality, the total rate is double that, at 7.8%.

On closer scrutiny of our individual cases in Table

Table 6

COMPLICATIONS ARISING OUT OF DIAGNOSIS AND THERAPY.

| *Complications* | *Carcinoma In Situ Cervix* | *Carcinoma Cervix* | *Carcinoma Endometrium* |
|---|---|---|---|
| Hemorrhage | 5 | 7 | 3 |
| Abscess | 4 | 4 | 2 |
| *Bowel Obstruction: | | | |
| Tumor Recurrence | 0 | 4 | 0 |
| No Recurrence | 0 | 5 | 6 |
| **Fistulae | | | |
| Tumor Recurrence | 0 | 6 | 0 |
| No Recurrence | 0 | 7 | 0 |
| ***Urinary Tract Injury (excluding fistulae) | | | |
| Tumor Recurrence | 0 | 11 | 0 |
| No Recurrence | 1 | 2 | 1 |
| Thrombophlebitis | 1 | 2 | 1 |
| Pulmonary Embolus | 2 | 4 | 2 |
| Pregnancy | 2 | 1 | 0 |
| Complete Skin Exfoliation | 0 | 1 | 0 |
| Mortality | 0 | 2 | 2 |
| Mortality Rate | 0 | 1.7% | 1.5% |

*all 9 had received prior radiotherapy for carcinoma of the cervix.
**11/13 had received prior radiotherapy for carcinoma of the cervix.
***11/13 had received prior radiotherapy for carcinoma of the cervix.

6, 6 of 13 cases were associated with cancer recurrence in previously irradiated patients. Furthermore, we have demonstrated what Boronow has commented upon, in that 6 of 13 had had combined radiotherapy and surgical efforts. Eleven patients had had prior radiotherapy, while two had had surgery alone. Four (3.5%) patients underwent either radiotherapy or surgery alone without other complicating events prior to the development of the fistula.

There were two mortalities arising directly from treatment of cancer of the cervix (1.7% mortality rate): one patient sustained a basilar artery thrombosis at age 58 on the evening of radium insertion, and the other patient sustained a massive pulmonary embolus at age 43 on the evening following exenteration. There were, likewise, two deaths in the endometrial cancer treatment group (1.5% mortality rate): one patient of septic shock at age 77 six days post-op, and one patient experienced a fatal pulmonary embolus at age 55 one day post radium insertion. Three of those were possibly preventable fatalities since the initiation of mini-dose heparin at our institution over the past few years. Whether or not we are creating further, or different, complications with this regime remains to be seen.

Our known late recurrence rate clinically (arbitrarily those patients with recurrence beyond Five-Year Survival) amounted to 7.4% (4 of 54) for all stages of carcinoma of the cervix and 4.8% (4 of 83) for all stages of carcinoma of the endometrium. This obviously cannot include those deaths from intercurrent illness on whom post-mortem examinations were not performed.

## Discussion

Since the main purpose of this study was one of self-evaluation, in order to offer our patients counseling from which they may decide where to seek medical care for potentially terminal illness, emphasis has not been placed on close scrutiny of diagnostic techniques, epidemiology, specific radiation dosages, etc. That will be addressed separately. Rather, an attempt has been made to arrive at figures that we may offer to the patient in order to enable herself to make that important decision of where to seek specific therapy, which for that individual means life or death.

A second purpose has become obvious with the evolution of this study: that is to stimulate other centers not solely entrusted to the delicate care of the cancer victim to do the same. Furthermore, I am hopeful that discussion and argument will follow concerning this important issue.

## Conclusion

Five-year survivals for epidermoid carcinoma of the cervix and adenocarcinoma of the endometrium appear to be within acceptable limits to continue the treatment of these cancers at this institution.

These malignancies appear to occur later in this rural population, since late detection alone would tend to contribute to large numbers of late stage disease and possibly poorer survival rates. In reviewing our own data there is recently a definite trend toward larger numbers of patients harboring carcinoma in situ compared to invasive epidermoid carcinoma of the cervix. This most likely is due to improved screening techniques and patient education and motivation.

Table 7

FISTULAE - 13 PATIENTS

| | (Months) Interval For Development |
|---|---|
| 1. RECTO-VAGINAL: radiation (combined*) alone—Stage IIIB—alive 13 years | 7 |
| 2. RECTO-VAGINAL: radiation (combined*) alone—Stage IIIB—dead of recurrence | 16 |
| 3. RECTO-VAGINAL: radiation (combined*) *plus recurrence*—Stage IIIA—dead | 16 |
| 4. RECTO-VAGINAL + VESICO-VAGINAL: radiation (combined*) *plus recurrence*—Stage IIIB—dead of recurrence | 23 |
| 5. RECTO-VAGINAL: surgery (Exenteration) alone—Stage IIIB—dead of recurrence | 1 |
| 6. RECTO-VAGINAL: radiation (external**) plus surgery (Wertheim) *plus recurrence*—Stage IIB—dead of recurrence | 22 |
| 7. RECTO-VAGINAL: radiation (external**) plus surgery (Wertheim) *plus recurrence*—Stage IIA—dead of recurrence | 38 |
| 8. RECTO-COLO-CUTANEOUS: radiation (combined*) plus surgery (Wertheim)—Stage IIB—dead brain abscess, pneumonia | 11 |
| 9. ENTERO-VAGINAL: surgery (Abdominal-perineal resex, colon carcinoma) plus radiation (combined*) *plus recurrence*—Stage IB—dead | 7 |
| 10. ENTERO-ENTERIC: radiation (combined*) *plus recurrence*—Stage IIIB—dead | 12 |
| 11. URETERO-VAGINAL: surgery (Wertheim) alone—Stage IB—alive 15 years | 1 |
| 12. URETERO-VAGINAL: radiation (combined*) plus surgery (Wertheim)—Stage IB—alive—22 year survival | 2 |
| 13. VESICO-VAGINAL: radiation (combined*) plus surgery (TAH, BSO for chronic pelvic inflammatory disease)—Stage IIA—dead 14 years after treatment of widespread recurrence | 12 |

*combined—intracavitary Radium plus Cobalt 60.
**external—Cobalt 60.

Outpatient endometrial biopsy over a 25-year period appears to be an effective diagnostic tool, as long as its limitations are realized, and thus avoiding time-consuming and costly inpatient evaluation.

We must strive harder to reach an older patient population with endometrial carcinoma reluctant to seek medical attention for seemingly obvious bleeding abnormalities, signaling a malignancy with generally slow growing and late metastasis behavior patterns.

Considering the age group with which we are dealing, our survival statistics would seem to indicate that uterine cancer can be managed in a way which may be somewhat more palatable to the patient, and thus encourage follow-up, than the rigors that attend city exposure.

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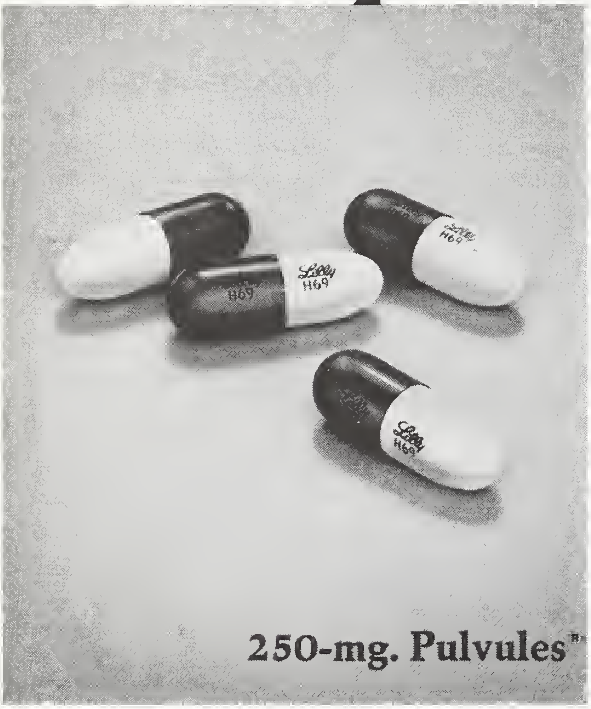

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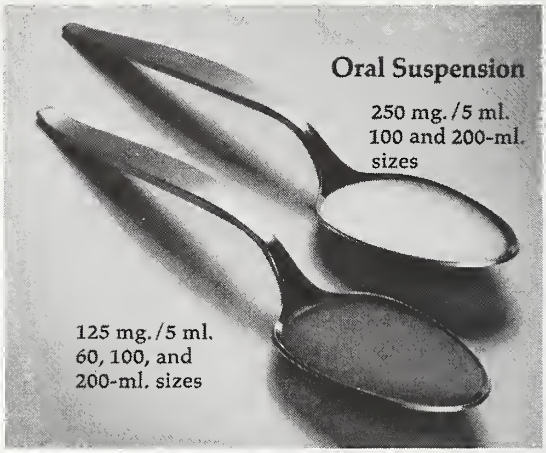

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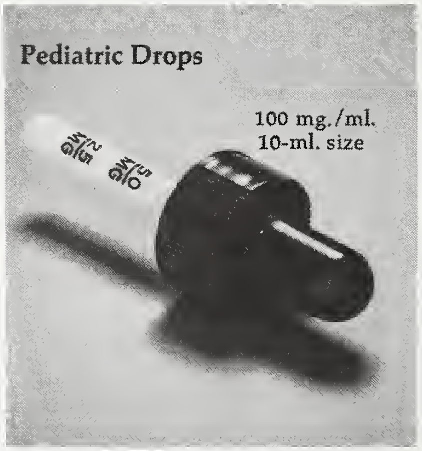

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# Trends in Surgical Treatment of Life Threatening Hemorrhage from the Large Bowel

## Introduction

DR. HASTINGS K. WRIGHT (Chief of General Surgery, Yale-New Haven Hospital): Until recently, bleeding from the large bowel has been one of the most difficult diagnostic and therapeutic challenges for intestinal surgeons. Lower gastrointestinal bleeding is often massive and often occurs in patients in the seventh and eighth decades of life who have severe coexisting cardiopulomary disease. Locating a specific bleeding point either before or during surgery was often impossible. Accordingly, surgeons tended to delay surgery until far more bleeding had occurred than would have been tolerated in a patient with a known site of upper gastrointestinal bleeding, and then to perform an emergency, last chance, subtotal colectomy in the hope of including the bleeding site in the resected colon specimen. The mortality rates of such procedures commonly exceeded forty percent.

Today with the advent of new diagnostic techniques including colonoscopy and selective arteriography, a specific bleeding site can often be located in such patients and less than total colectomy performed. In addition, the use of selective vasopressin infusion techniques, particularly in bleeding diverticulosis, and the use of transcolonoscopic resections of polyps and fulgeration of small tumors in the emergency situation may have improved the situation.

To clarify the present practice in Connecticut, we have asked four of the affiliated Yale Hospitals to search their records retrospectively for the last two years to find all such patients who have required emergency transfusion of at least 1000 cc of blood for colon hemorrhage and to report their results to us (Table 1).

DR. WRIGHT: These results certainly show dramatic improvement in the care of these patients. The combined 125 patients had a similar age distribution to that previously reported, ranging from 70 to 75 years on average. Between 20 and 25 percent of the patients in each hospital required emergency surgery for continued massive bleeding.

Table 1

MASSIVE COLONIC BLEEDING 1977-1978

| | | |
|---|---|---|
| No. of patients with colon hemorrhage | 125 | |
| No. of patients requiring surgery | 29 | (23%) |
| Mortality rate of surgical patients | — | ( 0%) |

Incidence of massive life-threatening colon hemorrhage and surgery in four Connecticut hospitals in a two year period, with a zero percent mortality rate following surgery.

The mortality rate of zero for the 29 patients undergoing surgery cannot be improved upon. This is a remarkable improvement over a decade ago when the mortality rate of emerging colon surgery approached 40% in many institutions.

We will now discuss the diagnostic workup and care of these patients. The first question to be asked is how far one should go in working up a patient admitted to the hospital with massive rectal hemorrhage who requires tranfusion.

DR. ORLANDO PELLICCIA, Assistant Chairman and Chief of General Surgery, Hospital of St. Raphael: As the statistics so well show, between 75 and 80 percent of these patients will stop bleeding after minimal transfusion—usually on the order of two to three units—and then can be worked up at one's leisure. I am very leery about taking octogenarians directly from the emergency room to the arteriography suite while they are hemorrhaging for what may turn out to be a two or three hour diagnostic procedure with the patient's vital signs under little observation. My personal belief is that these patients should be placed in a holding area under close observation, probably in an intensive care unit, given morphine to help decrease their bowel motility, and observed for at least 1,000 to 1,500 cc of blood loss. If the bleeding persists after this point,

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A Panel Discussion at Surgical Grand Rounds, Yale-New Haven Hospital, April 21, 1979.

then an aggressive diagnostic workup should be performed. The first step in most cases would be arteriography, which was successful 87% of the time in the 15 patients in whom it was tried. However, sigmoidoscopy and colonsocopy followed by barium enema also were highly successful when the clinical findings such as a mass in the abdomen or the clinical history were highly suggestive of a left-sided obstructing colonic lesion as the cause of the bleeding. In this series, 12 other patients had a diagnosis of left colon cancer or polyp made by colonscopy as soon as the acute bleed had subsided.

DR. WILLIAM QUIGLEY: Chief of Surgery, St. Mary's Hospital, Waterbury: The vast majority of these patients come in bleeding massively and then, very quickly, subside particularly if they have a mass lesion such as a carcinoma or bleeding from angiodysplasia. Some of the diverticular bleeds are massive and continue. I think the time to look for a cause is after the 1,500 cc blood transfusion mark, too, and at this point I would go directly to angiography.

DR. WRIGHT: What about the patient who spontaneously stops bleeding? Almost 80 percent of these patients did stop bleeding with treatment consisting only of blood replacement. Is further workup indicated early in the group who do not require emergency surgery to find a possible cause which would be helpful if they bled again?

DR. JAMES GUTHRIE, Attending Surgeon, Norwalk Hospital: I would limit workup in these patients to sigmoidoscopy on admission and a carefully performed barium enema several days later. A barium enema done during the immediate post-hemorrhage phase can restart the bleeding. It used to be said that the barium enema was occasionally therapeutic in that after its administration the patient often stopped bleeding. The evidence for this therapeutic effect was largely anecdotal and is outmoded now that arteriography and possible infusions of the bleeding site with vasopressin are available in most hospitals.

DR. QUIGLEY: Some groups believe that arteriography should be done on all these patients to find the patients with angiodysplasia. While one cannot often demonstrate extravasation of dye into the lumen in patients with angiodysplasia, the discovery of the angiodysplasia is used as an indication for surgery. I personally have not seen data to support the performance of angiography on all patients with major bleeding from the colon, and would prefer to follow them conservatively. Unfortunately, there is no specific finding in the history such as age or presence of cardiovascular disease which would lead me to pick out a subgroup who would require semi-elective angiography. Approximately half of the patients with angiodysplasia do have cardiovascular disease, usually valvular in nature. However, in our series, half of the patients who hemorrhaged from causes *other* than angiodysplasia also had cardiovascular disease.

DR. WRIGHT: I think we all agree that the immediate treatment of these patients is replacement of blood loss and the performance of a sigmoidoscopy. If bleeding persists and a bleeding point can be located by angiography or by colonoscopy where indicated, then is there any effective nonsurgical treatment?

DR. PELLICCIA: Vasopressin is very effective temporarily in controlling diverticular bleeding but is ineffective in controlling bleeding from angiodysplasia. Diverticular arterial hemorrhage is from one vessel, and it has been our experience, and Yale's as well, that in approximately three-fourths of the patients the bleeding can be temporarily controlled, and in the other fourth the bleeding can be permanently controlled. Recently, we have not had to take any patient to surgery in the middle of the might because of massive diverticular bleeds, but have been able to perform semi-elective procedures the next day. Unfortunately, we have had no luck with deliberate embolization of vessels, and have had one elderly patient who was not a fit subject for surgery develop necrosis of the sigmoid colon after gelfoam embolization.

DR. GUTHRIE: Fortunately, colonic bleeds due to angiodysplasia are usually relatively slow and the patient does not force the surgeon's hand in the middle of the night. A persistent slow ooze or the passage of large quantities of clot every five to six hours is the usual picture in our experience. One would not expect vasopressin to have much of an effect on these lesions, since it would be swept through to the venous side quickly and not cause arterial vasoconstriction.

I was very surprised at the low incidence of angiodysplasia in the patients undergoing emergency surgery in this series. Only one-fifth of patients requiring emergency surgery at these four hospitals had angiodysplasia as a cause. In contrast, recent reports from other institutions suggest an incidence ranging from 32 percent to over 50 percent. The difference may lie in the fact that in many hospitals an aggressive early diagnostic approach is taken on all patients with massive rectal bleeding. The four institutions represented here apparently did not follow a policy of immediate aggressive diagnostic workup including angiography and, therefore, would have missed some patients with angiodysplasia who undoubtedly then stopped bleeding.

DR. WRIGHT: The next problem is to decide when to operate on patients who continue to bleed. How much blood loss should be tolerated before these patients are taken to surgery?

DR. PELLICCIA: We are now following the same criteria that we use for patients with known causes of upper gastrointestinal bleeding: when they have required 5 or 6 units of blood, we prepare them for surgery, having already performed the diagnostic workup mentioned previously to prepare ourselves for this possible eventuality. I would no longer wait for a loss of ten to fifteen units, as in the past, when we could not make a specific diagnosis.

DR. QUIGLEY: One should now treat these patients like any other patient bleeding from the gastrointestinal tract and not wait for a prolonged bleed to take place. I might comment on the problem of the patient in whom no specific bleeding site can be found. Should he be treated differently from patients who are briskly bleeding from a known site? The evidence from these four hospitals suggests that this type of patient no longer exists. If the patient is bleeding massively enough to require surgery, a diagnosis can usually be made. In this series, it was made in 83 percent of the cases. Ten patients in this group died without surgery, but none was a surgical candidate, all being preterminal from some other cause. Thus, I believe that one should persist in an attempt to make a specific diagnosis in the patient who is briskly bleeding with the knowledge that one will be rewarded in finding a bleeding site. In most cases, the days of going to surgery without a specific known bleeding site are past.

DR. WRIGHT: What operations should be performed for specific known sites of bleeding in an emergent situation? First of all, what about the patient who has angiodysplasia demonstrated in the cecum?

DR GUTHRIE: I would perform a right colectomy and include at least the right half of the transverse colon. There is no evidence that hemicolectomy performed in this fashion carries any higher risk than a simple excision of the cecum alone. There have been numerous instances of rebleeding in patients with angiodysplasia probably because they have multiple angiodysplasias at the time of the first bleed and a second one lets loose at a later time. Almost all of these lesions are proximal to the splenic flexure, and I would think that a hemicolectomy would include most of them. I would add that there are reports in the literature of coagulation through the colonoscope of possible sites of AV-malformation, but I think successes are going to be few and far between because of the difficulty in locating the actual AV-malformation through the colonoscope. Indeed, I think that the actual coagulation of such a lesion would be obtained by luck. However, such coagulation has been performed in patients who have been actively bleeding and have been at least temporarily successful.

DR. WRIGHT: What about the patient with right-sided diverticulosis with a demonstrated site of bleeding in the right colon who is also known to have left-sided diverticulitis.

DR. PELLICCIA: I would perform only a right colectomy in these desperately ill patients. There is no doubt that the mortality rate of subtotal colectomy as an emergency is going to be higher than the zero percent rate reported here for these selected segmental resections.

DR. QUIGLEY: I would agree that right colectomy in the emergent situation is the procedure of choice with a bleeding diverticulum of the right colon, except under one condition, and that is when the patient is young and has universal diverticulosis. In such a case, with a long life expectancy, I would proceed with subtotal colectomy. However, such cases would be few and far between since, as our series points out, the average patient is 70 to 75 years of age with this problem. I would emphasize too that blind left colectomy should never be done for bleeding diverticulitis from an unknown site, since the majority of bleeding sites in these patients will be in the ascending colon.

DR. WRIGHT: Finally, I would like to ask about the patient who has been worked up and a specific bleeding site discovered who stops spontaneously before one can get to the operating room. Should these patients be operated on electively?

DR. QUIGLEY: I would not operate electively on a patient with angiodysplasia unless there was evidence of at least continued mild bleeding with guiac positive stools and anemia, or unless a second bleed occurred. I believe that until the long term natural history of this lesion (which has been demonstrated only within the last decade) is known, we should be conservative in operating prophylactically.

DR. PELLICCIA: With regard to diverticulosis which has stopped bleeding, I would not perform any type of elective procedure. None of the patients in this series with a diagnosis of diverticulosis had previously bled massively. This finding suggests that patients with diverticulosis seem to bleed once massively and then not bleed again. Therefore, I believe that elective resection in this elderly population would not be in order.

DR. WRIGHT: I wish to thank the participants in this symposium and also, particularly thank Dr. Higgins of Yale and Drs. Sreenivas and Gupta of St. Raphael's Hospital for looking up many of these cases for us. Thank you.

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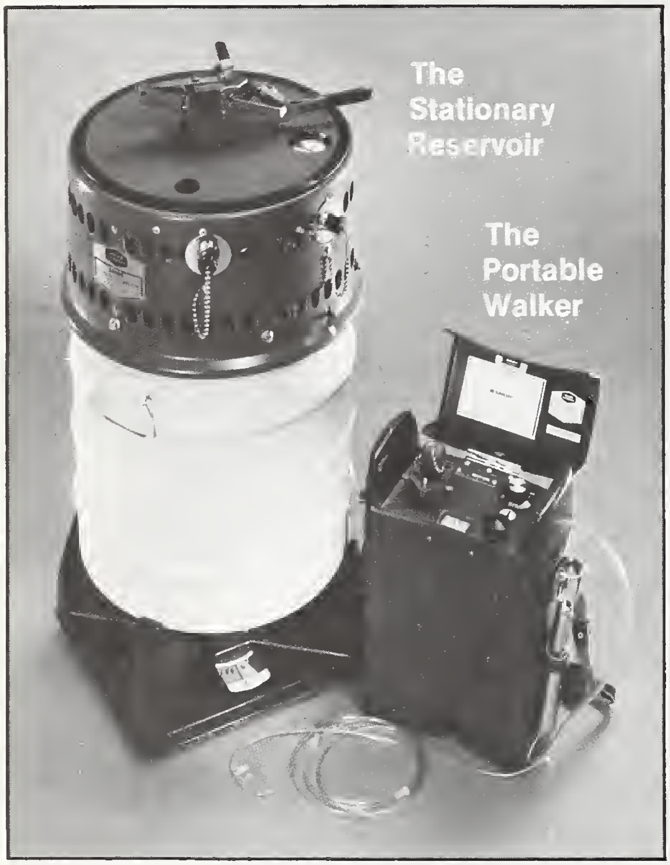

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# Prepared Natural Childbirth vs. Regular Labor and Delivery: Differences in the Outcome

ALFREDO J. HERRERA, M.D.

Prepared natural childbirth (Lamaze method) is quickly gaining acceptance around the country; however, the benefits of P.N.C. in the outcome of the delivery in mother and baby remains controversial.[1] [2]

### Material and Methods

We compared the outcome of the labor and delivery of 99 mothers who attended P.N.C. classes (Group I) with 100 others who did not (Group II). The two populations were socially matched.

### Results and Discussions

The differences in the outcome are shown in Table I, the age and gravity were similar. We did not find any difference in the incidence of Caesarean Section or duration of labor.

We did find a significant difference in the needs for analgesia and anesthesia—67% of the mothers in Group II required analgesia (Demerol) in an average dose of 76 mgm as compared to 54% of Group I in which the average dose was 30 mgm. This is of primary importance, mainly now when caution is being raised about the possible long term effects of Demerol on the infant.[3]

Similar significant differences were found in the needs for epidural (10% Group I vs. 30% Group II) and general anesthesia (1% Group I vs. 30%). Low forceps were more often applied in Group II (33%) than in Group I (21%). Again, this difference was significant but related to the maternal desire of "natural childbirth." The difference in the use of mid-forceps (5% vs. 10%) was not significant.

There were no differences in neonatal morbidity and mortality between the two groups. The Apgar scores at 1 and 5 minutes were comparable; however, 24% of the babies in Group II had an Apgar of 7 or less at one minute compared to 9% in Group I, a statistical difference and probably reflects maternal analgesia or anesthesia. These percentages decreased at 5 minutes to 3% and 0% respectively and were not significant. Also, 7% of infants in Group II required positive pressure breathing compared to none in Group I.

Table I

| | *GROUP I* | *GROUP II* | |
|---|---|---|---|
| Age | 25.7 yrs. | 25.7 yrs. | |
| Gravity | 1.4 | 1.7 | |
| Analgesia (Demerol) | 54% | 67% | $p < 0.05$ |
| Average Demerol per Patient | 30 mgm | 76 mgm | |
| Epidural Anesthesia | 10% | 25% | $p < 0.05$ |
| General Anesthesia | 1% | 30% | $p < 0.05$ |
| C/S | 12% | 13% | N.S. |
| Low Forceps | 21% | 33% | $p < 0.05$ |
| Mid Forceps | 5% | 10% | N.S. |
| Baby's Weight | 3400 | 3398 | |
| 1′ Apgar | 8.7 | 8.1 | |
| 5′ Apgar | 9 | 9 | |
| 1′ Apgar 7 or less | 9% | 24% | $p < 0.05$ |
| 5′ Apgar 7 or less | 0% | 3% | N.S. |
| Positive Pressure Breathing | 0% | 7% | $p < 0.05$ |
| Duration of Labor | 8 hrs. 22′ | 9 hrs. 40′ | N.S. |

The differences between the two groups reflect the degree of preparation in Group I. These mothers are aware of what labor and delivery are; they know what to expect and they are ready to cope with it.

Finally, parents in Group I described the process as a "joyful experience." This is very important since the public is asking us to bring deliveries "back to the family," and parents to be active participants. For all the above reasons, we believe P.N.C. is an important aspect of modern obstetrics and with "Birth Centers" may be a compromise to the growing idea of "home deliveries."

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ALFREDO J. HERRERA, M.D., Director of Nurseries, New Britain General Hospital; Assistant Professor, Department of Pediatrics, University of Connecticut School of Medicine, Farmington (at the time this paper was written April 24, 1979).

Dr. Herrera is presently Chief, Division of Neonatology, St. Agnes Hospital, Baltimore, Maryland 21229.

# Medical and Health News

A CHARGE OF CONSPIRING TO FIX OR STABILIZE FEES was brought against the Michigan State Medical Society by the Federal Trade Commission last week. According to the complaint, the society solicited "proxies" from members to authorize termination of contracts with Blue Cross and Blue Shield of Michigan and Michigan Medicaid if they didn't adopt reimbursement policies acceptable to the society.

Louis R. Zako, M.D., chairman of the MSMS Council, said the society has not seen the complaint. If it is similar to a draft reviewed several weeks ago, he said, it is "written so broadly as to restrict our Constitutionally guaranteed freedom of speech and would even prohibit MSMS from having input into cost containment programs."

The FTC complaint accuses MSMS of engaging in concerted actions to "restrict, regulate, impede or interfere with the health care cost containment or reimbursement policies of BCBSM or Michigan Medicaid." Said Dr. Zako, "Contrary to the opinion of the FTC, when cost containment is applied to health care and the development of reimbursement methods, they are legitimate concerns of physicians and of the Michigan State Medical Society."

He added: "We have had difficulty in getting people to listen to our views so, over past months, in utter frustration, the medical profession has taken some steps to make its views and opinions heard by Michigan Blue Cross-Blue Shield. However, the FTC has apparently misconstrued our intent and purposes in taking these actions. The MSMS will comply with federal law, but we will not give away our Constitutional freedoms which are threatened by the FTC complaint."

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AT THE INVITATION OF TWO CHIROPRACTIC ORGANIZATIONS, AMA officers met in September with officers of the American Chiropractic Assn. and the International Chiropractic Assn. In a letter to the 12 organizations that are codefendants with the AMA in lawsuits brought by chiropractors, the AMA reported that the meeting was "a face-to-face exploration of areas of mutual concern." No conclusions were reached, the AMA said, but lines of communication were opened.

The chiropractors' letter requesting the meeting was sent to the AMA's incoming President late in July and was signed by the board chairmen of the two chiropractic associations. It contained no reference to the pending litigation.

A preliminary meeting, authorized by the AMA Board of Trustees, was held Aug. 15 to explore the nature of the proposed meeting of officers. Representing the AMA at the preliminary meeting were the executive vice president and the deputy executive vice president. Topics for future discussion, suggested by the chiropractic representatives at the preliminary meeting, included upgrading chiropractic education and scientific studies to determine areas, if any, in which spinal manipulation is useful therapy.

AMA officers at the September meeting were the chairman and vice-chairman of the Board of Trustees, the president-elect, the executive vice president, and the deputy executive vice president.

The AMA letter reporting the meetings was sent to the American Academy of Orthopaedic Surgeons, American Academy of Physical Medicine and Rehabilitation, American College of Physicians, American College of Radiology, American College of Surgeons, American Hospital Assn., Chicago Medical Society, Illinois State Medical Society, Iowa Medical Society, Joint Commission on Accreditation of Hospitals, Medical Society of New Jersey and Medical Society of the State of New York.

—*AMA Newsletter*, September 17, 1979

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**References:**
1. Meyer, C.: American Folk Medicine. Scarborough, New York, Plum Books — New American Library, 1975, p. 208.
2. Data on file, MERRELL-NATIONAL LABORATORIES Division of Richardson-Merrell Inc. Cincinnati, Ohio 45215

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# The HMO Movement in Connecticut

MEHDI ESLAMI, M.D. AND ELLEN SEIGEL, M.A.

The "HMO" (Health Maintenance Organization) movement is alive and flourishing in Connecticut, and physicians who practice in this state should be attuned to the development of HMOs in their area and how their practice may be affected or involved.

Connecticut currently has five plans which are in various stages of the federal qualification process. They are: the New Haven County Foundation for Medical Care, the Physicians Health Services (Greater Bridgeport Medical Foundation, Inc.), the Fairfield Health Plan covering Fairfield County, the New London County Foundation for Medical Care, and the Eastern Connecticut Health Study in Storrs. In addition, four plans are already federally qualified, the Connecticut Health Plan (CHP) in Bridgeport and the Community Health Care Plan (CHCP) in New Haven, the North Central Connecticut HMO in Windsor Locks and the Southern Connecticut Community Health Plan in Stamford. In addition, physicians in Hartford, Middlesex and Litchfield Counties are currently considering various HMO alternatives. Simply put, an HMO is an organized system of health care

—providing comprehensive, continuous coordinated health care services

—through a specific group of physicians

—to a voluntarily enrolled group of persons within a particular geographic area

—on a fixed, prepayment basis.

The term HMO (Health Maintenance Organization), although loosely used to describe medical foundation plans or prepaid health plans, technically should be reserved for only those plans which have been designated as "federally qualified health maintenance organizations" by the federal government. The federal definition of an HMO first appeared in the federal regulations developed to implement the Health Maintenance Organization Act of 1973 (P.L. 93-222) and later the 1976 Amendments to the Act. The HMO Act was an attempt by the Nixon Administration to stimulate the development of prepaid health care systems. The Administration believed that prepaid plans would make comprehensive health care more readily accessible to the public. Federal planners were most impressed, however, with the record of those prepaid plans already in existence, notably the Kaiser plans which had consistently demonstrated a significant reduction in hospitalization expenses (as a result of fewer admissions and shortened hospital stays) by their patient population. Although subscribers to these plans tended to make greater use of outpatient services, because the more costly component of the delivery system, hospitalization, had been reduced, the plans were able to show an overall reduction in per capita expenses.

Enactment of the HMO Act was viewed by some as a more moderate approach to a national "socialized" health care system. Private enterprise was being given another opportunity to improve the delivery of health care in the United States while remaining free and willing contributors to the system. Within this spirit of free enterprise, the HMO Act recognized two different HMO Models:

1. Individual Practice Association Model (IPA, Foundation, or Open-Panel Plan) - Physicians are organized and provide services under a prepaid format but continue to practice in their own separate offices. The Foundation or IPA usually markets the HMO, does peer review, pays claims and establishes reimbursement formulas for participating physicians. The New Haven County Foundation for Medical Care (FMC), the Greater Bridgeport Medical Foundation (BHS), and the Fairfield Health Plan are examples of this type of HMO.

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MEHDI ESLAMI, M.D., a practicing radiologist in Waterbury was president of the New Haven County Foundation for Medical Care from its inception until 1978 when he was elected president of the New Haven Medical Association.

ELLEN SEIGEL, M.A. is Assistant Director of the New Haven County Medical Association and the New Haven County Foundation for Medical Care.

2. Group Practice Model (Closed Panel Plan) - A group, or number of groups, of physicians practicing together, sharing facilities, medical equipment, records and personnel. CHCP, CHP and the North Central Connecticut HMO are examples of this other type of HMO.

The federal regulations written to implement the HMO Act require an HMO applicant to complete four studies: feasibility, planning, initial-development and qualification, prior to being designated as a federally qualified program. At each phase, the applicant generally submits a grant application, and receives federal funding to undertake and complete the study. The completed study is then submitted with an application for the next phase. Logically, the first study, feasibility, attempts to determine whether the development of an HMO is feasible for the proposed service area. Specifically, the applicant must consider the issue of feasibility with respect to five specific program components:

1. Legal: Are there any legal barriers which would prevent the establishment of any HMO in the area?
2. Providers: Are there a sufficient number of providers who would support the establishment of the HMO and would agree to become providers for the HMO?
3. Actuarial Analysis: Is the plan able to provide a specific package of benefits as required by the HMO regulations? What would be the monthly premium to provide these services?
4. Financial: How will the HMO support itself during the initial start-up period? At what membership size would the HMO reach a break-even point?
5. Marketing: Is there a sufficient population in the area which might enroll in the HMO? Are there a sufficient number of firms in the area who might offer the HMO to their employees? How does the HMO's premium compare to the premiums of existing health options currently being offered to these employees?

When the feasibility study is completed, the applicant generally applies for a planning grant under which planning for the five program components identified in the feasibility report may be initiated. An application for Initial Development of these components then follows Planning. The entire process (generally consuming from 3-5 years) culminates with an application for Qualification and the certification plaque from the federal government which indicates that the plan is a federally qualified Health Maintenance Organization.

Throughout this process, there are numerous site visits by federal officials and the juggling of project staff and consultants employed for the studies. Table 1 summarizes HMO development throughout the State of Connecticut at the present time.

In the April 1978 issue of Connecticut Medicine, Robert W. Doering, M.D., described the development of the Greater Bridgeport Medical Foundation (PHS). The authors of this present article have been involved with the New Haven County Foundation for Medical Care (FMC) and can report many similarities in the development of PHS and FMC. Both plans

Table 1

STATUS OF HMOS IN CONNECTICUT

| *Name of Plan* | *Service Area* | *Model* | *HMO Status* |
|---|---|---|---|
| Connecticut Health Plan | Greater Bridgeport | closed-panel | Qualified |
| Community Health Care Plan | Greater New Haven | closed-panel | Qualified |
| Eastern Connecticut Health Study | Windham, New London, and Middlesex Counties | closed-panel | Feasibility application submitted |
| Fairfield Health Plan | Fairfield County | open-panel | Planning Study Underway |
| Greater Bridgeport Medical Foundation (Physicians Health Services) | Greater Bridgeport | open-panel | Planning Study Underway |
| New Haven County Foundation for Medical Care | New Haven County | open-panel | Planning Study Underway |
| New London County Foundation for Medical Care | New London County | open-panel | Feasibility application submitted |
| North Central Connecticut HMO | Windsor Locks | closed-panel | Qualified |
| Southern Connecticut Community Health Plan | Stamford | closed-panel | Qualified |

were sponsored by local medical societies who opted to support an open-panel HMO. More than 280 physicians have signed participating physician agreement contracts with PHS, and FMC (whose service area covers all of New Haven County) now lists more than 550 physicians as participants in the program.

One interesting difference in the two programs is the method of physician reimbursement. While the PHS plan pays physicians according to a "set of fees mutually agreed upon by each specialty", FMC reimburses physicians according to their own personal fees which are reported to the Plan at the time the physician joins the program. FMC's computer systems have calculated within each specialty the 80th percentile fee for each procedure performed within the specialty. The plan will reimburse the participating physician his usual and customary fee unless his fee is higher than the 80th percentile (i.e., that amount which 80 percent of the physicians in the specialty are charging either at, or less than), in which case the physician is paid only at the 80th percentile fee. Once the reimbursement fee is determined, FMC like PHS withholds 20 percent of the fee for administrative start-up costs and as a hedge against any unanticipated claims exceeding premium income. Should the funds withheld not be utilized, there is the chance that all or part of this money can be returned to the physicians at the end of the year, in proportion to their contribution into the fund. This risk sharing money is an incentive for the physician to eliminate unnecessary services, to shorten hospital stays and to be willing to review the activities of his or her colleagues.

The HMO movement is apparently widespread in Connecticut. Of the two HMO models (open panel versus closed panel) we believe that the open-panel (Foundation) plan has the greatest potential for attracting members and physicians. Because physicians continue to practice in their own offices, the open-panel model maximizes the likelihood that a physician in private practice would consider becoming affiliated with the HMO. For the subscriber, the open-panel plan increases the likelihood that his or her personal physicians are on the list of the HMO's participating physicians. Thus the subscriber can reap the benefits of a comprehensive prepaid health plan without giving up physicians they wish to continue seeing.[1]

Physicians who practice in Connecticut are urged to become more active in those open-panel plans being developed in their areas. Regardless of whether you support the concept or are ambivalent, HMOs are a reality in Connecticut which will benefit from your involvement.

## REFERENCES

1. Although the original HMO Act allowed for the two types of HMOs: Group Practice and Individual Practice Association (IPA or Foundation Plan), the record of the Federal government to date, has been to encourage the more rapid development and federal qualification of Group Practice HMOs.

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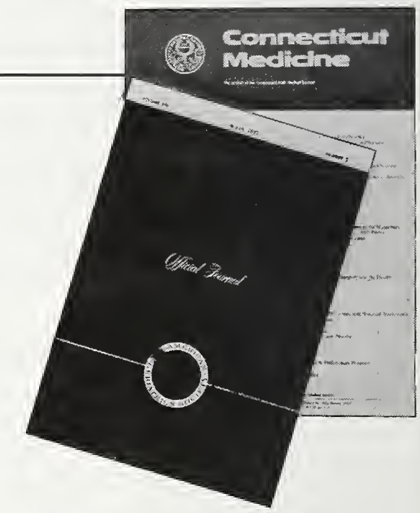

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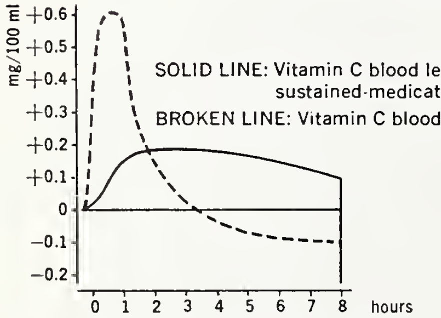

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# Mass Screening for Colorectal Cancer

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### Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

This is one of a series of consensus development meetings to examine aspects of medical technology which may be ready for broad scale demonstration programs in the community and to develop useful information which can serve as the basis for public and physician education programs. The objective of the conference held on June 26-28, 1978 was to evaluate the scientific evidence related to colorectal screening. A detailed summary and meeting proceedings are in preparation.

Many disciplines were represented on the conference agenda including gastroenterologists, epidemiologists, oncologists, surgeons, pathologists, economists, internists, and family practitioners. The steering committee consisted of Dr. Joseph T. Painter (chairman), Vice President, University of Texas Systems Cancer Center; Dr. Thomas P. Almy, Third Century Professor of Medicine, Dartmouth Medical School; Dr. George Hutchison, Professor of Epidemiology, Harvard School of Public Health; Dr. Charles G. Moertel, Chairman, Department of Oncology, Mayo Graduate School of Medicine; and Dr. Paul Sherlock, Chairman of Department of Medicine, Memorial Sloan-Kettering Cancer Center. Although all methods of screening and early detection were covered, the conference primarily examined stool occult blood testing as a screening technique for colorectal cancer. A number of studies were reviewed, including the results of clinical trials for occult blood testing for detection of colonic neoplasms in the U.S. and Germany. Proctosigmoidoscopy as a screening tool was not discussed in detail, as it is known that physician utilization has been low secondary to poor patient and physician acceptance of rigid sigmoidoscopy.

The steering committee has agreed to the following recommendations as applied to screening. These recommendations do not apply to persons who present with symptoms which could be related to colorectal cancer who will require complete diagnostic workup which might include any or all of the tests mentioned.

1. There are insufficient data to date to indicate that screening for colorectal cancer by stool occult blood testing reduces mortality from the disease in screened populations participating in clinical trials. More time is needed for the ongoing clinical trials to collect enough additional data before it will be possible to assess survival benefit, risk possibilities, and economic feasibility. Although it is recognized that decisions must sometimes be based on incomplete evidence, caution is advised in the development of public policy recommendations about population screening programs for colorectal cancer at this time.

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Copies of booklet "NIH Consensus Development Conferences Summaries from 1977-78," may be obtained from the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205. Copies of 1979 individual conferences are also available.

This recommendation is based upon the absence of a clear demonstration of (a) improved survival rates in screened individuals with colon cancer or (b) a net margin of benefit to health in comparison with the costs and risks entailed in the further study of all positive occult blood reactions by barium enema or endoscopy.

2. Until more knowledge of the benefits and risks of screening for this cancer site is available, mass screening demonstration programs should not be initiated by the Division of Cancer Control and Rehabilitation, NCI.

3. Additional clinical investigations are strongly urged before occult blood testing can be endorsed for general use. However, because the method is commercially available for unregulated use by practicing physicians or other health care service providers, the following guidelines for professional use are recommended:

a) a statement that benefit/cost/risk indices cannot be determined at this time;

b) a statement that in the light of present information, the uncontrolled application of the method outside of special evaluation studies may not represent a wise use of health care resources and may not be of benefit to the recipients of the intervention;

c) where used the technique should be limited to asymptomatic men and women over the age of forty unless there are additional personal or familial risk factors;

d) where used the procedure should include:

- meat-free high fibre diet prior to testing
- storage of specimens for less than 4 days before testing
- no rehydration of slides when using Hemoccult II slides
- the recording of all results as positive or negative. Doubtful readings should be recorded as negative and trace readings as positive
- the handling of a single positive slide as if all slides are positive

e) at present all positive tests should be followed by complete examination of the colon by radiological and/or endoscopic means;

f) follow-up expertise and facilities for diagnosis and treatment should be readily available; and

g) fecal occult blood testing should not be used at present as a substitute for proctosigmoidoscopy or as a basis for clinical decisions in patients with symptoms of colorectal cancer.

4. The major controlled clinical research trials which are evaluating colorectal cancer screening using occult blood testing should be continued. These are (1) the evaluation of occult blood testing performed annually in a study group as a part of the patient examination in the Preventive Medicine Institute—Strang Clinic in collaboration with the Memorial Sloan-Kettering Cancer Center; and (2) an evaluation of occult blood testing in combination with a diagnostic protocol in a control group, an annual screening group and a biennial (every 2 years) screening group at the University of Minnesota.

5. Since all evaluations of screening must be geared to the proper interpretation of the pathology including all the histologic variations in adenomas and the premalignant and malignant changes that may occur within them, the development of a uniform interpretation and nomenclature is needed. Workshops for this purpose may be useful.

6. Professional organizations should educate the radiological, medical and surgical communities regarding the importance of an air contrast study in addition to the standard barium enema in the radiological examination of the patient suspected of having a colonic neoplasm or a small polypoid lesion.

7. Professional organizations should encourage the assumption of responsibility by physicians for adequate cleansing of the colon in preparation for barium examinations. The risk and expense of this examination are not justified in poorly prepared patients.

8. The following are recommended to clarify the role of flexible sigmoidoscopy:

a) comparison of the value of flexible sigmoidoscopy with that of rigid sigmoidoscopy in a total program of detection of asymptomatic colonic neoplasms;

b) the evaluation of the possibility of training general internists and paraprofessionals to use flexible sigmoidoscopes adequately;

c) comparison of the relative value of several different lengths of the flexible sigmoidoscope for examination by screening physicians; and

d) comparison of the value of flexible sigmoidoscopy plus air contrast barium enema with that of endoscopy of the total colon (colonoscopy). The combination of flexible sigmoidoscopy and air contrast barium enema is considerably less expensive and may be more generally available. If the two are equally effective in a screening setting, the less expensive flexible sigmoidoscopy and air contrast barium enema could be an alternative approach.

9. The following are recommended in high-risk groups:

a) the organization of cooperative studies to establish the proper surveillance procedures for high-risk groups. Currently, there are no available data on the choice of surveillance methods for the followup of these patients. High-risk groups include persons with inflammatory bowel disease (both ulcerative and granulomatous colitis), persons with various familial polyposis syndromes, persons with a strong family history of site-specific cancer of the colon, persons in cancer families where colon cancer, endometrial cancer, and breast cancer seem to be clustered, and patients who have had a previous adenoma of colon cancer removed. Cooperative studies in high-risk groups may be of value in the evaluation of diagnostic procedures, the effects of diet on the prevention of cancer and other population studies.

b) the development of at-risk profiles and registries of those at high risk. Various centers need to pool and exchange information about profiles and to perform identifying tests requiring skills not available at every center.
c) the investigation of dye scattering techniques and other methods to identify dysplastic lesions. These should reduce the need for multiple biopsies in patients with ulcerative colitis.
d) the development of innovative approaches to identify persons in the general population who are at high risk for colon cancer not included in the known high-risk groups above.

10. Research to identify immunologic and biochemical markers in colonic washings, blood, and urine should be strongly encouraged.

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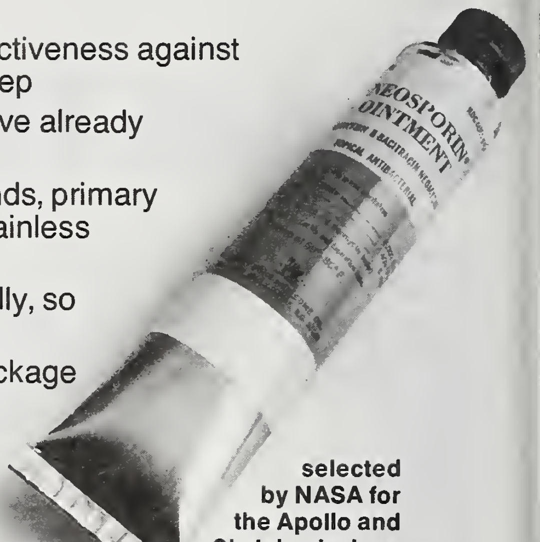

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# Current Legal Developments Concerning Hospital Privileges for Podiatrists

WERNER STRUPP, J.D.

The policy of the American Podiatry Association (APA) in furtherance of members' legal rights in respect to hospital privileges has taken several forms. At the outset, it should be stated that legal action has for many years been regarded as a measure of last resort. The initial emphasis has continued to be on negotiation. This has brought about the gradual recognition of the proper role of podiatrists in the standards of the Joint Commission on Accreditation of Hospitals, as well as in Federal and state legislation dealing with hospital matters. Recent statements of the American Medical Association have also affirmed that podiatrists should be granted the opportunity to practice in hospitals, subject to evaluation of their individual qualifications.

The desire to resolve conflict where hospital privileges for podiatrists are concerned, by discussions and persuasion, has not deterred the Association from taking strong and decisive action when it was warranted by the circumstances. This has been the case particularly in recent years, both as a result of the educational and professional advancement of podiatry and as a consequence of the aggravated restrictive practices which have been brought to bear on the efforts of many podiatrists in seeking appropriate clinical privileges in hospitals.

The most concentrated and sustained support in any legal action in this area has been the case of *Shaw v. Hospital Authority of Cobb County.** In this case, which has been in progress since 1973, the issue of categorical exclusion of podiatrists from hospital privileges has been brought into the sharpest focus. APA filed a friend of court brief in the U.S. Court of Appeals and participated in oral arguments. The opinion of the appellate court, which remanded the matter for further hearings, contained important language that identified a constitutionally protected liberty interest that qualified podiatrists have in gaining access to the facilities of a public hospital. The appellate court held that this liberty interest entitled a podiatrist to hearings that conform to minimal standards of procedural process. In addition, however, the Court required that these hearings focus on the underlying constitutional right, namely the liberty interest to practice one's own chosen occupation or profession. Accordingly, the due process hearings must be more than empty formalisms and/or gestures—a fundamental right is involved.

APA assisted Dr. Shaw's counsel in presenting the case at the hospital hearings which followed the appeal. Unfortunately, the hospital authority once again denied Dr. Shaw's application for change of the bylaws to enable podiatrists to obtain privileges. The District Court was once again asked to review the matter. It held that the due process requirements imposed by the Court of Appeals had been appropriately met by the hospital. The Court sustained the class distinction between podiatrists and orthopedic surgeons as being reasonably related to the management of the hospital's affairs. The Court continued to agree that the services that podiatrists could perform are already more adequately rendered by orthopedists. A second appeal has been noted. APA has actively collaborated in the preparation of briefs at the trial court and appellate levels. The Georgia Podiatry Association has also filed an *amicus curiae* brief in support of Dr. Shaw's position, and the American Medical Association has submitted an *amicus* brief on behalf of the hospital authority. Oral argument has not yet been scheduled. APA continues to regard this case to be one of major importance to the profession.

Another law suit of great significance to podiatry is a case in which three podiatrists in the Dallas, Texas,

*U.S.C.A.-5, 507 F.2d 625 (5th Cir. 1975).

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WERNER STRUPP, J.D., General Counsel, American Podiatry Association, Washington, D.C.

area challenged the actions of a hospital board which had arbitrarily reduced their previously held privileges.* Without any reference to individual qualifications, the podiatrists suddenly found themselves relegated to technician status. They could perform surgical procedures only with the concurrence of medical doctors who possessed privileges in the particular specialty involved, i.e., orthopedic surgery. It is obvious that those kinds of ground rules would have permanently destroyed the podiatrists' ability to perform surgery at this hospital. The podiatrists filed suit in state court on various grounds, including violation of civil rights, conspiracy, defamation and invasion of privacy. After a jury trial of several weeks, a verdict was returned in favor of the podiatrists on more than 150 counts. Compensatory damages of $550,000 and punitive damages of $1,000,000 were assessed by the jury against the hospital, and the court enjoined the further attempts to interfere with the podiatrists' exercise of their lawful privileges. An appeal in this case is now pending.

Several other legal actions in which APA has been less directly involved are still in progress. In two different state courts in Ohio, podiatrists have challenged their exclusion from staff privileges merely on the grounds that they are podiatrists. Most recently, suit has been filed by a podiatrist in a South Carolina Federal Court to deal with a substantially similar situation. In addition to the legal proceedings that have been referred to, a number of cases in different states are either in the status of actual preparation or are under active consideration. Among those are cases in North Carolina, Rhode Island, Georgia, New Jersey, Michigan, Florida, Indiana, and Virginia. An even greater number of states are represented in the many letters and telephone inquiries which APA has received from individual members and component societies who are considering legal actions. While every instance presents some factual distinctions, it is fair to say that the pattern of class discrimination, which is the focal point of the above-mentioned litigation, is readily apparent in every single case.

APA's efforts to bring about an improvement in the recognition of the legal rights of podiatrists in hospitals is not limited to the mentioned litigation. The Association continues to encourage component societies to seek amendments to hospital licensing statutes or regulations that would require consideration of applications by podiatrists for clinical privileges on the basis of their individual merit. Nine states have now adopted such rules, or have arrived at the same result by administrative determination.

APA has also been in extensive communication with the Federal Trade Commission on the same subject. This is based on the contention that the activities of organized medical groups in denying podiatrists access to hospitals represents an illegal restraint of trade. The denial of hospital privileges to podiatrists frequently appears to be the result of concerted action by members of medical groups acting with or without the collaboration of the governing boards of hospitals. Because of the jurisdiction that the FTC has in matters involving possible violation of the antitrust laws, it is believed to be highly appropriate that APA request that the FTC take action in these cases. The FTC is engaged in a comprehensive investigation of hospital staff admission practices. APA will follow this investigation closely and will continue to direct the Commission's attention to the problems here discussed. Likewise, the attention of the anti-trust division of the U.S. Department of Justice is being called to these matters.

Finally, and certainly not least in importance, has been the Association's attempt to obtain meaningful references to the services of podiatrists in Subpart J of the Social Security Regulations. These regulations contain minimum standards for participation of hospitals in the Medicare program. In most respects these regulations have not been revised since 1966—before podiatry was included in the Medicare law. Podiatrists are physicians under Medicare; it is highly important that their status be clearly spelled out in the regulations, rather than being left to inference and interpretation. The Federal regulations should not sanction any discrimination against a group of licensed practitioners as a class, and staff selection in hospitals should be required to proceed entirely by reference to professional qualifications. The Government's proposed revisions of these regulations have been under study for several years. Publication of the new regulations is expected in the near future.

The importance of these Federal regulations cannot be overestimated. In view of the fact that Medicare participation is essential for all hospitals, the effect of these rules is indeed far-reaching. Not only would these regulations supersede any standards of the Joint Commission on Accreditation of Hospitals with which they may be in conflict, but they will also become the model for state regulations dealing with the licensure of hospitals.

The long and tedious struggle of establishing the legal rights of podiatrists is far from completed. However, there can be no doubt that gradually courts and legislatures are being persuaded to the view that members of an independent profession that by law may treat by medical, surgical, and other means can no longer be excluded as a class from meaningful access to modern hospitals. Not only will our system of government finally refuse to tolerate such practices, but more importantly, the patients whom all health disciplines serve will demand this fundamental fairness.

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*Miller et al v. Charter Medical Corp. et al, 193rd Judicial Circuit of Texas (Dallas County).

# Activities of the Department of Foods and Nutrition of the American Medical Association

CONSTANCE J. GEIGER, M.S., R.D.

The American Medical Association has been a leader in furthering the science of nutrition since 1929. The nutrition-related activities of the American Medical Association during the years 1929-1974 have been summarized previously by P.L. White: "A Brief History of the AMA's Council on Foods and Nutrition," *Nutrition Today* 10(1):10-14, 1975. Many of the activities described in that article are still ongoing programs of the Department of Foods and Nutrition. This report is a summary of new programs, recent changes and expansions of older programs and activities not previously described.

Since 1975, the Department of Foods and Nutrition has worked with the support of consultants and the *ad hoc* committee called the Nutrition Advisory Group. Activities of the Department are carried out by a staff of 6 nutritionists, a food scientist and a technical editor.

### Nutrition Education, Professional

*Medical School curricula:*—Efforts are underway in medical schools to provide education in both normal and clinical nutrition. Nutrition as taught in medical schools, however, has not kept pace with advances in the field. Realizing the need to expand and improve nutrition education in medical schools, the Department of Foods and Nutrition has, over the years, been engaged in suggesting general guidelines for the integration of nutrition into medical education. Surveys have been conducted and conferences have been held to study the status of nutrition in medical education.[1 4] Recommendations have been offered for consideration for developing new programs in nutrition education and for integrating nutrition into existing medical curricula.

The Chicopee Conference on Teaching Nutrition in Medical Schools was held in 1962 by the AMA to define and establish guidelines for the integration of nutrition into medical education. Prior to that time, undergraduate teaching in nutrition was focused primarily on nutritional deficiency diseases and did not deal with the new advances in nutrition.

As a result of the Chicopee Conference, the AMA's Council on Foods and Nutrition issued the statement on the "Nutrition Teaching in Medical Schools."[1] Recommendations of the Council included improvement and expansion of existing nutrition education programs and the establishment of additional clinical teaching and research programs in both medical and dental schools. Continuing medical education and postgraduate programs were proposed to keep the practicing physician abreast of current concerns and developments in nutrition.

The Williamsburg Conference on Guidelines for Nutrition Education Programs was held in 1972 as a follow-up to the Chicopee Conference.[2] The impediments to development and expansion of teaching nutrition in medical schools were reviewed and the slow progress in incorporating nutrition into the medical school curriculum was lamented. The participants again formulated and updated guidelines and recommendations for integrating nutrition into medical school curriculum. These were distributed to U.S. medical schools. Since that time, regional conferences have been held to assist in the development and expansion of nutrition in medical school curricula.

The importance of nutrition in medical education and practice has been increasingly recognized in the last seven years. At the Williamsburg Conference in 1972, only six medical schools were identified as providing specific courses in nutrition. By 1974, a mail survey conducted by the Department of Foods and Nutrition revealed that 57 of 85 medical schools (67%) had "identifiable course material" on nutrition within their curricula.[3]

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CONSTANCE J. GEIGER, M.S., R.D., Nutritionist; Section of Nutrition Education, Department of Foods and Nutrition, AMA.

In 1976, a mail survey was conducted of the 114 U.S. medical schools that were accredited at the time.[4] Of 102 schools responding, 19 (19%) offered a required nutrition course, 72 (70%) offered electives in nutrition, and 94 (95%) offered nutrition within the framework of other courses. Twenty-seven schools (28%) offered clinical clerkships in nutrition, 81 (80%) offered research opportunities in nutrition and 30 (31%) provided postgraduate or continuing medical education courses in nutrition.

In order to continue monitoring the status of nutrition education in medical schools, the survey was repeated in 1978. Questionnaires were sent to 124 accredited U.S. medical schools. Of 118 schools providing usable responses, 30 (25%) required a course in nutrition, 84 (71%) offered electives in nutrition, and 106 (97%) incorporated the teaching of nutrition into other courses. Forty-three medical schools (37%) had a clinical clerkship in nutrition, 100 (85%) had nutrition research opportunities for students, and 58 schools (50%) provided continuing medical education or offered opportunities for postdoctoral training in nutrition.

The average length of the required courses in nutrition was 20 hours. These courses most often were known as Principles of Clinical Nutrition, Nutrition, and Modern Nutrition in Health and Disease. In addition to the concepts of normal nutrition generally taught, subjects of clinical relevance were included. Elective courses were most often taught in the clinical years and were interdisciplinary. The average course length was 20-40 hours of lecture time.

Nutrition information was found to be incorporated into as many as 30 different courses and clinical clerkships. This incorporation ranged from a few hours of structured lectures to as many as five weeks of instruction in a single course.

Clinical clerkships in nutrition were most frequently presented as electives. These were usually preceptorships with a physician in charge of a nutrition support service. Research opportunities in nutrition were available in medical schools in the basic or clinical sciences. A majority of the schools indicated that the research had to be initiated by the students.

A number of formats were used for the continuing medical education or postgraduate studies in nutrition: grand rounds, conferences, visiting lectureships and courses. Subjects covered included Nutrition in the Practice of Medicine, Nutritional Support of the Hospitalized Patient, and Trace Elements in Human Nutrition.

The results of the 1978 survey demonstrated a significant increase in the amount of nutrition incorporated into the medical school curriculum since 1976: required courses in nutrition increased by 32%; elective courses, 1%; nutrition incorporated into other courses, 2%; clerkships in clinical nutrition, 32%; research opportunities in nutrition, 6%; and continuing medical education or postgraduate courses in nutrition, 61%.

A registry of nutrition courses in medical schools, including sample curricula, is maintained by the Department. These are available upon request to those schools interested in developing or expanding their own curricula. Follow-up surveys are being planned to monitor progress in this area and to determine how the Department of Foods and Nutrition can be of further service in stimulating interest in nutrition.

*Scholarships:*—The Department has expanded its activities in recent years to stimulate further development of nutrition education within medical schools. For 21 years, the Department has offered scholarships in nutrition to medical students. In 1976 the 18-year-old program of *research* fellowships in nutrition was modified to provide *clinical* emphasis and became the program of "Joseph Goldberger Scholarships in Clinical Nutrition." Clinical centers of special competency were identified and invited to develop clerkships (6 to 10-week period of supervised clinical work) in clinical nutrition and to accept outside students. Fifteen medical schools now offer clerkships in nutrition to outside students. An average of 25 students per year are sponsored by the Department to take advantage of this opportunity.

*Conferences and publications:*—Several conferences have been held for the purpose of (1) reviewing recent advances in clinical nutrition, metabolism, and patient care and (2) making such information available to medical students, physicians and other health professionals. The most recent Conference, held in November, 1978, dealt with the topic, "Sodium-Potassium in American Foods." Books based on these conferences have been published (or will be published):

Fat Emulsions in Parenteral Nutrition - 1976
Defined-Formula Diets for Medical
  Purposes - 1977
Clinical Nutrition Update: Amino Acids - 1977
Nutrition in Transition: Proceedings, Western
  Hemisphere Nutrition Congress V - 1978
Sodium-Potassium in American Foods - (Late
  1979)

*Nutrition in Transition* is a full report of the most recent Western Hemisphere Nutrition Congress (August, 1977, Quebec City), which the AMA cosponsored and staffed. Publications based on these triennial Nutrition Congresses provide updates in virtually every aspect of nutrition. The Sixth Congress will be held in Los Angeles in August, 1980.

The Department of Foods and Nutrition works in concert with other departments of the AMA to provide information to physicians and other health professionals. The scientific journals and "American Medical News" provide opportunities for publishing current information and opinions on nutrition. As another example, the AMA Division of Continuing Medical Studies sponsors hundreds of postgraduate courses. A number of these courses are related to clinical nutrition and are developed by the Department of Foods and Nutrition.

### Guidelines for Nutrition in Intravenous Preparations

Some years ago the Food and Drug Administration declared parenteral multivitamin preparations "ineffective as currently formulated." Because of the critical medical importance of parenteral multivitamins in certain conditions, and the lack of alternative drugs for this purpose, the FDA decided that such products should remain on the market until appropriate reformulation could be agreed upon by experts. Under the direction of experts serving as the Nutrition Advisory Group, the Department of Foods and Nutrition developed guidelines that provide rationale for the need of these products in medical practice as well as guidelines for product composition and clinical testing for safety and efficacy. The document, "Guidelines for Multivitamin Preparations for Parenteral Use," was submitted to the FDA in 1975. Further, in 1977 the Nutrition Advisory Group directed the Department in establishing a working group of experts for the purpose of developing "Guidelines on Essential Trace Elements in Intravenous Nutrition." These guidelines were submitted to the FDA in December, 1978, and have since been published (*JAMA* 241:2051-2054, 1979). It is expected that the AMA will continue to take leadership in the area of intravenous nutrition.

### Nutrition Education, Public

Although the Department has a primary commitment to provide information and assistance to physicians and medical students, time and effort are also devoted to education of the public.

The Department's consumer-oriented book on foods and nutrition, "Let's Talk About Food," was first published in 1967 and its most recent revision was in 1974 (PGS Publishing Co., Littleton, MA). Written in question and answer style, this book reflects one kind of public educational effort in which all members of the Department are continuously involved. Requests for information are received each day from the public. Responses provided by the staff to questions such as the following serve as basis for the book:

> Can you tell me about the weight-reduction clinics that give hormone injections?
>
> What foods contain potassium?

Staff members also provide information on food and nutrition topics to media representatives; serve as a resource for writers in establishing scientific accuracy; give lectures to schools and community groups; and develop pamphlets and other literature for the public. A recent example of the latter is the booklet on "The Healthy Approach to Slimming."

The Department also, upon request, assists physicians and their patients in locating appropriate information in regard to special dietary problems, e.g., sources of information on food allergies or the cholesterol content of foods.

In recent years, there has been a vastly increased interest in nutrition by the profession and public as well as the Federal Government and its Congressional Committees. The Department of Foods and Nutrition has responded to proposals and hearings on matters such as Nutrition Labeling, U.S. Dietary Goals, the Sale of Non-Approved Competitive Foods to Children on Social Premises, and Nutrition and Medical Education.*

Probably the most difficult task of the Department is that of combating nutrition misinformation, although this is a facet of many educational efforts directed to the public. The Department continually speaks out against pseudo-science and provides factual information to assist the public in making wise decisions about food, nutrition and health.

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*Copies of these reports are available upon request from the Department of Foods and Nutrition at the American Medical Association.

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# A Comparison of Quality of Care on a Teaching and Non-Teaching Service in a University Affiliated Community Hospital

MARVIN GARRELL, M.D. AND JAMES F. JEKEL, M.D.

**ABSTRACT—The quality of the process of care was compared for teaching and non-teaching medical services of St. Vincent's Medical Center, Bridgeport, Connecticut, as determined from hospital discharge abstracts, using the method of procedural end points. The attending physicians were the same for both services, and the patients were randomized between the services, although this randomization was apparently incomplete. The patients cared for on the teaching service were more likely to have basic examinations performed and have adequate monitoring of patient progress. The findings have been fed directly into the educational process of the Medical Center.**

The problem of measuring quality of care is receiving intensive study at the present time.[1] [2] Methods employed frequently include measures of *structure* (e.g. resources, such as the number and type of facilities, equipment, type of administration and the number and qualifications of professional staff), *process* (i.e. the way these resources are delivered to patients), and *outcomes* (i.e. end results, such as mortality, morbidity, functioning, comfort, and satisfaction with care).[1] [2] It is usually conceded that structure is the easiest to measure but is the least satisfactory method of measuring quality of care. Conversely, outcomes are usually considered the most meaningful, but they are difficult to interpret. A third, increasingly popular approach is to study the process of care. Occasionally this involved observation of the process [3-6] or simultaneous data collection from both patients and physicians.[7] These approaches are valuable but expensive, and they involve a considerable period of delay until the information becomes available, so they are not adequate for ongoing "monitoring" of the care process, which is needed by those responsible for maintaining the quality of care in hospitals, clinics, or group practices.

Among the process indicators, a popular type is the "procedural end point," often called an "intermediate outcome." Procedural end points are *conditional* care events in the sense that given the existence or occurrence of something else, they should (or should not) occur. For example, given a hemoglobin level in the patient of less than 10 grams %, general anesthesia should not be administered except in extreme emergencies. Although these approaches do not measure final outcomes, they are fairly straightforward and easy to monitor, and they provide an indication of the extent to which physicians and other care persons adhere to currently accepted medical standards.

Difficulties in applying the technique of procedural end points include: 1) the fact that an appropriate procedure may have been performed but not recorded; 2) extenuating circumstances may have rendered the usual rules inoperative, yet these circumstances may not be possible to detect on discharge data forms; 3) the end points chosen, even though appropriate, may not indicate the total quality of care; and 4) these end points, in general, omit measures of the "art of care," the importance of which has been emphasized.[8] Nevertheless, despite the limitations, procedural end points represent a

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useful method of monitoring a large amount of inpatient medical care with a minimum of physician input.

One established system for measuring procedural end points (and a few selected outcomes) is the Quality Assurance Monitor (QAM) of the Commission on Professional Hospital Activities (CPHA) in Michigan. This system is based on a uniform hospital discharge dataset obtained from hospital charts by trained medical abstractors. The data for the present study were obtained from the QAM hospital discharge abstracts from the medical service at St. Vincents Medical Center, Bridgeport, Connecticut.

### Impact of a Residency Program on Quality of Care

A postgraduate medical education program is a costly commitment for a hospital to support. The continued existence of these programs has been justified because of the apparently obvious conclusion that we must continue to train the next generation of medical practitioners; and that the presence of a postgraduate teaching program will improve the quality of care given to patients by all of the practitioners working in that hospital.

Despite the importance of the issue, there are surprisingly few studies of the impact of a teaching program on quality of care. This is undoubtedly due partly to the difficulties of designing a study adequate to demonstrate a casual relationship between a teaching program and quality of care, and the even more difficult task of determining a cost-effectiveness ratio for the educational commitment. In the absence of careful design statistical association does not prove causation. For example, the most qualified practitioners may choose to work in a teaching hospital and the "better" hospitals may be able to attract more qualified house staff.

A similar methodological problem arises within a hospital: if there is a teaching service (TS) and a non-teaching service (NTS), and the quality of care is shown to be better on the teaching service. This may be due to the fact that the better qualified staff participate on the teaching service and admit their patients there. Therefore, an observation that the quality of care is better on a TS may lead some to an unjustified conclusion that the teaching program is responsible. On the other hand, both a TS and NTS may receive benefits from a teaching program, resulting in small or nonexistent differences in quality of care between them. In this circumstance, comparing quality of care on a TS and a NTS may cause one to *underestimate* the impact of the teaching program on the care process.

It would be ideal to be able to compare two hospitals that were very similar with respect to patients, quality of physicians, and resources, but one of which had, and the other lacked, a teaching program. To our knowledge, no such study has been done with adequate measures. As a more limited study, with more limited conclusions, one could compare the quality of care within one hospital by contrasting the TS and NTS in the same hospital, if the patients of all physicians were randomly assigned to TS or NTS.

One study was found in the literature which did, in fact, perform the second type of research.[9] It was done in the early 1960's on the medical service of St. Vincent's Hospital, Worcester, Massachusetts. The authors used a combination of CPHA discharge data and their own record analysis to describe their findings. Medical patients were randomly allocated to the TS and NTS, and they were similar on general characteristics and primary diagnoses. The authors found that the house staff, who guided the care on the TS, were somewhat more vigorous in their diagnostic workups (from 5 to 20% more of the patients received appropriate procedures.) Nevertheless, the differences were not as striking as one might have supposed. A similar study was done on the medical service of St. Vincent's Medical Center, Bridgeport, Connecticut, in the years 1974 and 1975, and is the subject of this report.

### Objectives of the Study

One of the objectives of the affiliation agreement between the Department of Medicine, Yale Medical School, and the eight affiliated community hospitals in Connecticut (of which St. Vincent's Medical Center is one), is to study the quality of patient care and methods to improve that care.[10] One of the first efforts in this direction was a joint effort of the Department of Medicine of St. Vincent's Medical Center and the School of Medicine to study the impact of the post-graduate medical education programs on the quality of care in the community hospitals. St. Vincent's Medical Center had been participating in the QAM system for a number of years and wanted to use the system to study differences in the quality of care on teaching and non-teaching services. Therefore, the first objective of the study became: to compare the quality of care on the teaching and non-teaching medical services at St. Vincent's Medical Center in Connecticut from January 1, 1974, through December 31, 1975, using the data from the QAM system.

### Location

St Vincent's Medical Center, Bridgeport, Connecticut, is a voluntary, nonprofit community hospital with a total of 390 beds, including 144 on the medical service. It has a separate coronary care unit (CCU) and intensive care unit (ICU). The hospital is fully accredited for residency training in internal medicine and has a major teaching affiliation with Yale Medical School in internal medicine. All staff physicians are required to participate in the teaching program. All orders for patients on the teaching service are written by the house staff, although the attending physician has final veto power for a given course of treatment.

### Study Sample

During the calendar years 1974 and 1975, medical patients (other than those admitted to the CCU or ICU) were assigned to the TS or NTS according to a process that was thought would produce randomization. This was accomplished by a policy that each new patient was to be assigned to whichever service had the first empty bed. Neither the private physicians nor the residents could alter the random assignment, except that a terminal patient being readmitted could be readmitted to the same service as the previous admission if a bed were available on that service.

Because the ICU and CCU were part of the teaching service, the study was done only on patients from the TS and NTS who had not been admitted to those units. The final study group consisted of 6978 discharges, of which 1319 (18.9%) were from the NTS and 5659 (81.1%) were from the TS. The TS and the NTS were not geographically separated in the hospital, so that the nursing care was presumed to be comparable on the two services.

### Data Sources

The data source was the standard CPHA QAM discharge dataset, on which was also recorded whether or not the patient was on the TS or NTS. These data were abstracted from the medical record by carefully trained and supervised medical records abstractors. In order to monitor the accuracy of the discharge abstracts, randomly selected hospital charts were regularly reviewed by the medical record supervisor and the director of medical education and compared with the discharge abstracts. The abstracted records were sent to the CPHA, which put the data onto computer tape. The data tape was analyzed at the Yale Computer Center using the AUTOGRP interactive statistical program developed by the Institution for Health Studies at Yale.[11]

### Comparison of the Study Groups

The two study groups were compared for demographic and medical characteristics. They were generally similar, but there were enough differences to question the hypothesis of complete randomization. For example, the mean age on the TS was 59 years, and that on the NTS was 55 years. There was no difference in the sex distribution, but those on the NTS were slightly more likely to be white (94% vs. 91%). Those on the TS had a somewhat greater average length of stay, due primarily to fewer admissions of two days or less (24% of patients on the NTS vs. 10% of patients on the TS). The primary differences in the payment method were that the patients on the TS were more likely to have Medicare (11% vs. 7%) but less likely to have Blue Cross or Commercial Insurance (49% on the TS vs. 61% on the NTS). This difference may be partly explained by the fact that the TS patients were somewhat older.

For most categories of disease, the two study groups had similar proportions of patients. For three categories of illness, the TS had a higher proportion of patients in that category: "Ischemic Heart Disease (11% vs. 9%), cerebrovascular accident (8% vs. 5%) and disease of the lung (8% vs. 5%). In one category, the NTS had a higher proportion: "Special Exams Without Illness" (4% vs. 2%).

Because the patients on the two services were not identical, the question arises as to whether there is any value in proceeding with further analysis. Because of the differences between the study populations, the outcomes were not compared. However, the criteria studied here either were considered essential regardless of diagnosis or were diagnosis-specific, so that the study group differences should have had little impact on a comparison of the intermediate outcomes studied.

Also of concern was whether the patients' *physicians* were randomly assigned to the TS and NTS. With one exception, all of the 51 physicians with more than 14 patients during the two years had patients admitted to both services; the one had 25 patients admitted to the TS and none to the NTS. Therefore, essentially all of the active physicians had patients admitted to both services.

The data studied here are merely representative of the kinds of data that can be obtained, emphasizing one condition (diabetes mellitus) and illustrating comparisons on: 1) general diagnostic procedures, 2) disease-specific diagnostic procedures, 3) inappropriate procedures, 4) monitoring of therapy, and 5) dataflow system problems.

### General Examinations and Tests

Table 1. shows the proportion of patients on the TS and NTS who had at least one of the listed tests recorded in the chart. In general, 10 to 20% more of the patients on the TS were likely to have had the tests and examinations recorded. On neither the teaching nor the non-teaching services were the three indicator physical examinations (funduscopic, rectal, and pelvic examinations) performed on anything approaching 100% of the patients.

Rectal and pelvic examinations were recorded on fewer than ½ of the patients on both the services. These percentages were slightly improved when only those patients over the age of 40 years were considered. However, routine chest x-rays, laboratory studies (blood sugar, BUN), and electrocardiograms were performed on 78% or better of patients over 40 on both services. These tests are apparently less objectionable than the physical examination items by both the house staff and the attending physicians. It is also possible that the attending physicians may recently have recorded some of the physical examinations on their office records and not bothered to transfer the information to the hospital chart.

Table 1

COMPARISON OF GENERAL PROCEDURES PERFORMED ON MEDICAL PATIENTS, TEACHING AND NON-TEACHING SERVICES ST. VINCENT'S MEDICAL CENTER, BRIDGEPORT, CONNECTICUT 1974 AND 1975

| | *Teaching Service* | | *Non-Teaching Service* | |
|---|---|---|---|---|
| *On All Discharged Patients* | N = 5659 | | N = 1319 | |
| | No. | % | No. | % |
| Funduscopic Examinations | 3356 | (59.3) | 508 | (38.5) |
| Rectal Examinations | 2789 | (49.3) | 474 | (35.9) |
| Pelvic Examinations | 218 | ( 7.1)* | 80 | (10.8)* |
| *On Discharged Patients Over 40* | | | | |
| Funduscopic Examinations | 2769 | (59.7) | 410 | (40.1) |
| Rectal Examinations | 2365 | (51.0) | 397 | (38.9) |
| Chest X-Ray | 4211 | (90.7) | 824 | (80.6) |
| Blood Sugar | 4136 | (89.1) | 813 | (79.6) |
| BUN | 4247 | (91.5) | 833 | (81.5) |
| EKG | 4091 | (88.2) | 792 | (77.5) |

*of females

## Disease-Specific Diagnostic and Therapeutic Items

Table 2 shows the number and proportion of patients with any diagnosis of diabetes mellitus who had received selected tests or therapies. Despite its diagnostic importance in diabetes, still less than ⅔ of the patients in both groups received a funduscopic examination. No differences were noted between services in preference for insulin vs. oral hypoglycemic agents.

Patients on the TS were somewhat more likely to have a BUN (92.3% vs. 87.2%) and other kidney function test (6.9% to 3.6%), but these were somewhat less likely to have a cholesterol level (21.5% vs. 35.7%) and 2 hour post prandial blood sugar (9.0% vs. 11.2%) or glucose tolerance test (7.1% vs. 10.7%). There did not appear to be any important differences in the approach to the care of diabetes between the two services.

The data on steroid therapy were of interest. In some cases the diabetes might be secondary to the steroid therapy. The medical staff has now established a routine to check on cases of steroid therapy in the presence of diabetes to determine if some patients could possibly be put on other treatment than steroids. However, in most cases the steroid therapy was indicated, despite the presence of diabetes.

Table 2

USE OF SELECTED EXAMINATIONS, TESTS, AND THERAPY ON PATIENTS WITH ANY DIAGNOSIS OF DIABETES MELLITUS MEDICAL SERVICES, ST. VINCENT'S MEDICAL CENTER BRIDGEPORT, CONNECTICUT

| | *Teaching Service* | | *Non-Teaching Service* | |
|---|---|---|---|---|
| *Patients with any Diagnosis of Diabetic Mellitus* | N = 963 | (17%) | N = 196 | (15%) |
| | No. | % | No. | % |
| Funduscopic Examination | 600 | (62.3) | 105 | (53.6) |
| Oral Hypoglycemic Agents | 350 | (36.3) | 66 | (33.7) |
| Insulin Therapy | 365 | (37.9) | 67 | (34.2) |
| Systemic Steroid Therapy | 72 | ( 7.5) | 11 | ( 5.6) |
| EKG done | 853 | (88.6) | 173 | (88.3) |
| Kidney Function Test | 66 | ( 6.9) | 7 | ( 3.6) |
| Two Hour PP. Glucose | 87 | ( 9.0) | 22 | (11.2) |
| GTT | 68 | ( 7.1) | 21 | (10.7) |
| BUN | 889 | (92.3) | 171 | (87.2) |
| Cholesterol | 207 | (21.5) | 70 | (35.7) |

Among patients with sugar in the initial urine sample, over 90% were followed up by some kind of blood sugar test.

## Monitoring of Therapy

Table 3 shows procedures performed on patients receiving antibiotics, diuretics, and anticoagulants. Among patients receiving antibiotics, over 3/4 had had a culture taken. Not all infections require a culture (e.g., cellulitis), and not all of the cultures require an antibogram (e.g., streptococci in a pharyngeal culture). Therefore, even though it appears that physicians on the teaching services are somewhat more careful in handling infection, without further clinical information it is impossible to know how many indicated tests were omitted, or how many needless tests were done.

There was little difference between the proportion of anticoagulated patients on the two services who received prothrombin time determinations (85% vs 87%) but the house staff were somewhat more likely to order a stool test for blood (Table 3). This has been chosen as another area for emphasis in the medical education program.

## Dataflow System Problems

In 1976, only 18 of 77 patients with a positive serology had a diagnosis of syphilis found in the chart or any indication that the positive test was noted. This was found to be due to a systems problem: when the hospital screening VDRL was positive, the serum was sent to the State Laboratory for a more definitive serologic test. By the time these reports were returned, the patient often had been discharged, so that the

Table 3

MONITORING TESTS PERFORMED ON MEDICAL PATIENTS WITH THREE DIFFERENT THERAPIES (ANTIBIOTICS, DIURETICS, AND ANTICOAGULANTS), TEACHING AND NON-TEACHING SERVICES

| | *Teaching Service* | | *Non-Teaching Service* | |
|---|---|---|---|---|
| *Patients Receiving Antibiotics* | N = 1526 | (27%) | N = 248 | (19%) |
| | No. | % | No. | % |
| Culture Taken | 1339 | (87.8) | 192 | (77.4) |
| Antibiogram Done | 857 | (56.2) | 108 | (43.6) |
| *Patients Receiving Anticoagulants* | N = 389 | ( 7%) | N = 55 | ( 4%) |
| | No. | % | No. | % |
| Prothrombin Time | 330 | (84.8) | 48 | (87.3) |
| Stool Test for Blood | 133 | (34.2) | 12 | (21.8) |

physician either did not know about the diagnosis or performed any subsequent tests outside the hospital, so that the final diagnosis did not get into the hospital chart. Currently the system has been changed so that the medical record analyst is alerted to a positive serology, and she redeposits the medical record in the physician's file with a request for a diagnostic decision and for an appropriate therapeutic response. A random review of 63 charts done in 1978 revealed that all charts with a report of a positive serology had evidence of physician awareness of the positive test, with appropriate response, although almost half of these needed some prodding from the medical records analyst. This effort is more than an attempt to treat the charts: it is a method of assuring that important test data are seen and dealt with, so that patients needing therapy will not be missed. Moreover, the follow-up to this problem uncovered some systems problems in the venereal disease control program at the state and local level, which have also been addressed.

## Discussion

Although it was hoped that this study would represent a true randomized trial, the evidence of incomplete randomization suggests that caution should be used in interpreting the data. Nevertheless, because of the nature of the data analysis, the design was considered adequate for the study of process variables. This study was done at much less cost of physician time than the Stapleton and Zwernemann study, because it used an already developed data system; to the extent that medical care studies can be done with an ongoing data system, they will be cheaper and more likely to be accomplished.

The findings were generally similar to those of Stapleton and Zwernemann, that patients on a teaching service receive a somewhat more thorough initial workup and closer monitoring of therapy than those on the non-teaching service. The difficulty lies in the conclusions to be drawn. Should we be disappointed that the differences were not greater? Certainly there was room for improvement, even for the teaching service. Or should we be pleased that the differences were relatively small? We should probably not be surprised that the quality of care appears to be similar on the two services, because the same attending physicians are the primary teachers for the house staff, and they supervise the care of the patients on both services. Moreover, one should be cautious in making the assumption that more tests are always better.

A study such as this cannot answer the fundamental question of the contribution of a teaching program to the quality of care, because a good teaching program would be expected to benefit *all* of the staff physicians, and therefore the patients on all services. The differences noted here, therefore, probably reflected a specific contribution to patient care made by the house staff in addition to the general benefit of the teaching program to all of the physicians.

One of the primary contributions of a study such as this is to indicate the importance of continuous monitoring of patient care to determine areas where medical practice needs improvement. Such ongoing monitoring is crucial to a relevant, problem-oriented educational program, but it is seldom feasible in the absence of a large scale, computer-assisted data system.

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# Reflections from the Dean's Office

## Costs, Character, and the Common Good

ROBERT U. MASSEY, M.D.

Several of us were discussing with some regulators the need for the most useful of the new technologies in university teaching hospitals, especially in those that admitted many referred patients. These hospitals have a double mission of teaching and patient care, and sharing a CT scanner, for example, with a distant institution might result both in poor patient care and bad education. The two are necessarily linked. Transporting a critically ill patient to another hospital for some needed procedure, especially if there is risk, is not first-rate medicine, good education, or sound economics. The regulator said that all depends upon the cost, that one must juggle risks, benefits, and costs. Everything, after all, he said, was a matter of economics. Or politics, he might have added. Leaving out politics, I suppose we could decide to deny surgery to patients 65 or older. That might save 20 or 30 percent of our health costs, which could then be spent for oil.

It is dangerous to conclude that everything is finally reducible to the terms of one thing or another, that all human behaviour is simply an expression of economics, or politics, or the unconscious, or neurotransmitters. I asked the regulator if he didn't believe that behind the economics of politics there were questions of value, and that maybe most decisions were ethical. He repeated that it all finally came down to a matter of cost.

Bacon, foreseeing the power of inductive reasoning, said that the new science and technology must be "for the uses of life." Deciding about the common good, for Bacon, would not have been as difficult as for us; he had Aristotle's formal system of ethics, but also there was in the sixteenth century a moral consensus to which anyone could refer, no matter how ignorant he might be of the formal system of the schools. Adherence to that consensus, sometimes called the natural law, was a matter of character, and knowledge of it a matter of common sense. As physicians we are obliged to intrude upon these decisions which the regulators and planners are trying to make. Since we are neither formal ethicists nor economists, and rarely understand politics, we can only fall back on what Ramsey has called "the moral character of the ethical physician (i.e., his 'steady state' for acting in commendable ways)."[1]

In a recent article, *Medical Ethics and Living a Life*, Robert Coles asks, "How broad and deep ought such a subject cut—to the bone of a doctor's life?"[2] He observes that, more than the philosophers and ethicists, the novelists "know how seamless a web life is, how significantly each physician's career connects with his or her moral values." About George Eliot's Middlemarch, Coles writes:

> "A doctor's character is proved wanting, and the result is his professional success by the standards of the time. Such a devastating irony leaves the reader in hopes, no doubt, that a bit of contemplation will take place: a person's work is a person's life, and the two combined as lifework must be seen as constantly responsive to the moral decisions that we never stop making, day in and day out. What George Eliot probed was character, a quality of mind and heart sadly ignored in today's all-too-numerous psychological analyses."

Decisions may be good or bad ethics depending on the soundness of the system and the precision of the logic, but the *rightness* of day-by-day decisions depends upon the character of those who make them. In the twentieth century's climate of ethical relativism, this must be so, because without a moral consensus, who can say that Kant or Aristotle had the better system, or that Jefferson's idea of the common good was better than the Ayattolah Khomeini's?

This is all terribly important in planning services for teaching hospitals, as well as in setting the content of medical education. Bad decisions about the care of the elderly and the quality of nursing homes may be made for reasons of costs or votes; goods and services, being finite, have to be rationed somehow, and political masters have to be elected.

There will continue to be struggles between the regulators, the administrators, and the doctors over the rightness of these decisions; there will be some hypocrisy written or spoken about the public good. This can not be avoided, and should be accepted. Sometimes saying the right things, even for political reasons, leads to right actions because of the commitments carelessly made. The value of the outcome, however, will depend upon the character and virtue of those who finally take the initiative and make the decisions.

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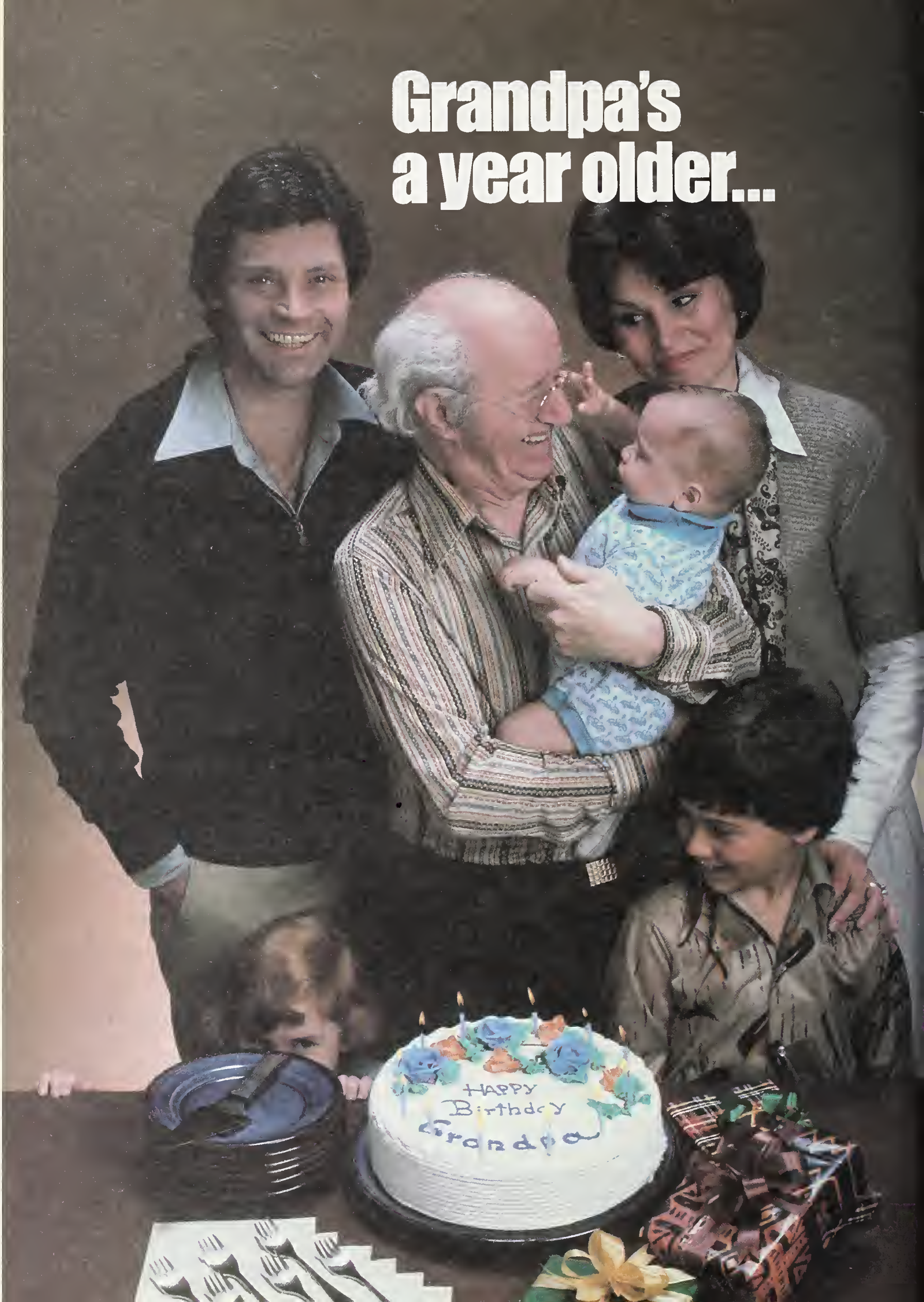
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Birthday
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# The Legal Rights of Minors in the Health Care Process I

JOSEPH M. HEALEY, J.D.

The legal status of minors has long been a source of confusion and uncertainty in our society generally, and in the health care process particularly. Are minors entitled to the same legal rights as adults or does the difference in status justify a difference in treatment? This issue has arisen in a variety of health care contexts including reproductive decision making and the civil commitment process. During its 1978-1979 term, the United States Supreme Court considered two cases dealing with this critical issue and the decisions in these cases provide assistance in understanding the legal status of the minor in these two important contexts. This month's column will focus on the mental health process, while next month's will focus on the reproductive decision-making context.

Under the process of voluntary commitment for mental health treatment, a patient enters a health facility without the procedural safeguards which must be present if he/she is forced involuntarily to enter a facility for treatment. The assumption is that the person is acting freely and is not being coerced in the voluntary commitment process. This assumption has been challenged in several cases involving minor patients since parents have had the legal authority to commit the minor without the minor's agreement or despite the minor's objection. In the case of Parham v. J.L., children being treated in Georgia state mental hospitals challenged the adequacy of the procedures for protecting the rights of minors during the process of admission to a state hospital for the treatment of mental illness. The Georgia commitment statute allowed a minor to be committed upon the application of a parent or guardian, provided the superintendent of the facility determined that there was evidence of mental illness and that the child was suitable for treatment. The statute allowed a parent or guardian to request discharge after a child had been hospitalized for five days and required the superintendent to release any child who had recovered from the mental illness or whose improvement made hospitalization no longer desirable. The plaintiffs in this suit contended that the Fourteenth Amendment required that an adversarial hearing before an impartial tribunal precede commitment as a way of assuring that the minors actually needed treatment and were not being inappropriately institutionalized for other reasons. The Supreme Court decision focussed on the question whether a minor has a constitutional right to an adversarial hearing before a parent's application for commitment of the minor to a mental health facility is acted upon.

In the majority opinion, Mr. Chief Justice Burger reviewed the legal history of the parent-child relationship. He found that a child has a substantial interest in not being confined unnecessarily for medical treatment. However, he was not convinced that the only, or the best way to protect the child's interests was to require an adversarial hearing in all cases:

> In defining the respective rights and prerogatives of the child and parent in the voluntary commitment setting, we conclude that our precedents permit the parents to retain a substantial, if not the dominant role in the decision, absent a finding of neglect or abuse, and that the traditional presumption that the parents act in the best interests of their child should apply. We also conclude, however, that the child's rights and the nature of the commitment decision are such that parents cannot always have absolute and unreviewable discretion to decide whether to have a child institutionalized. They, or course, retain plenary authority to seek such care for their children, subject to a physician's independent examination and medical judgment.

The Court went on to point out that the risk of error in a parental decision requires that there be an inquiry by a "neutral factfinder," to determine whether the statutory criteria for admission are present. This person must have the authority to refuse any admission should these criteria not be met. This "neutral factfinder" need not be a lawyer or a judicial or administrative officer. It is also unnecessary that there be a formal adversarial hearing. It is sufficient that there be an independent medical decision-making process and periodic review of the child's status. The Court concluded that the Georgia statute satisfied the requirements of the Fourteenth Amendment and, therefore, rejected the claims of the plaintiffs.

The decision raises many important questions. In terms of the legal rights of minors, the decision avoids recognizing a minor as entitled to the full rights of an adult and also rejects the suggestion that parents have absolute control over their children. In rejecting the extreme positions, the Court sought to establish a balance between the competing rights and interests. It remains to be seen whether that fine balance can be realized in practice. More on the rights of minors will be discussed next month.

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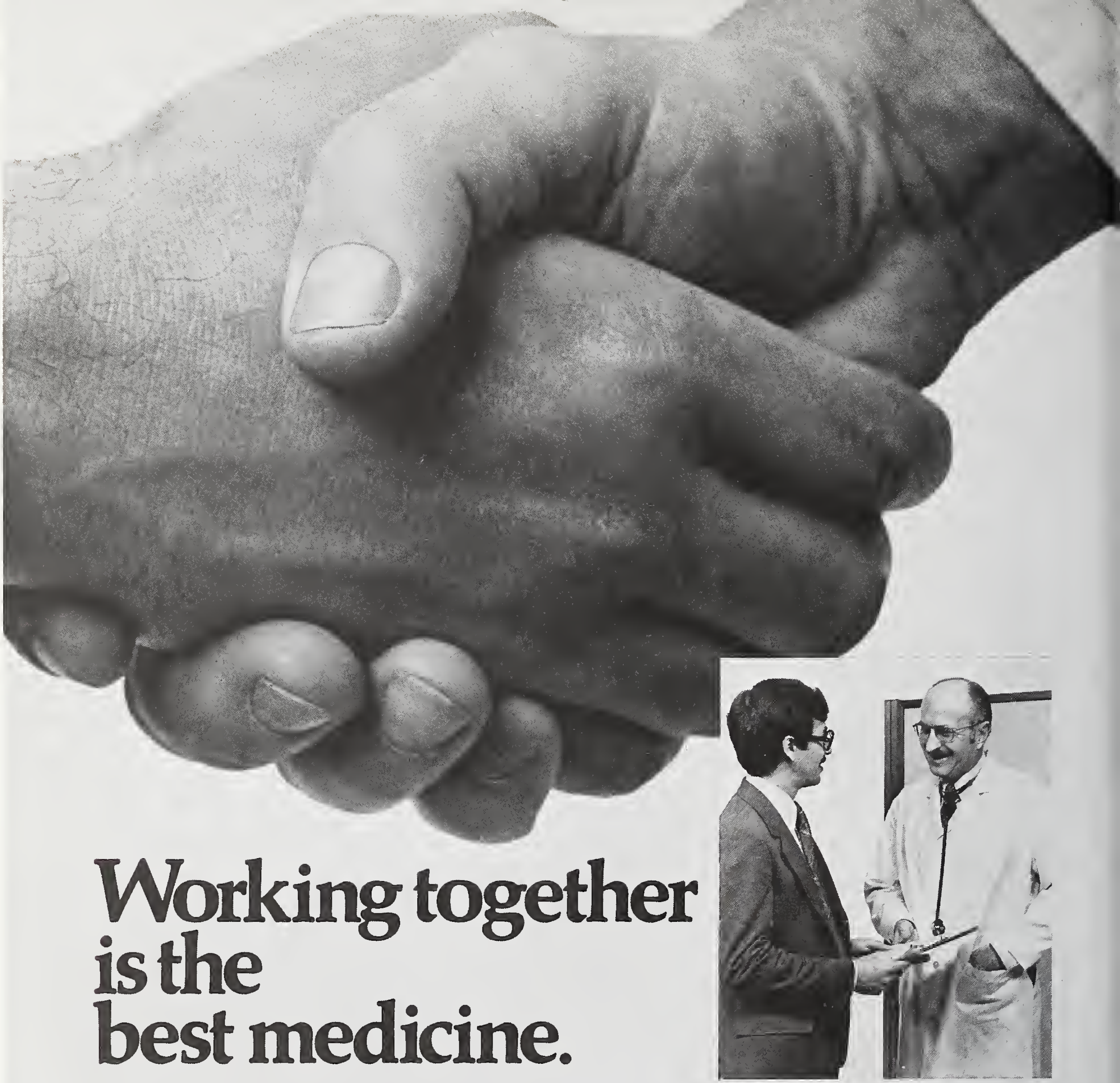

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# EDITORIALS

## National Health Insurance

The issue of National Health Insurance has been a matter for congressional and medical debate for more than three decades; the choices are more varied but the essential ingredient is government funding and control. Multiple forces have become increasingly vocal, and our Congress is more compliant with the need for political expediency. Reports by Washington savants indicate the strong probability that some version of National Health Insurance will pass Congress this session. I am amazed at the enthusiasm shared by our legislators and labor groups who have had an opportunity to review the effects of that "National Health" in Great Britian—deteriorating facilities, long waits, and emigration of physicians to other countries.

I remain unconvinced that nationalizing health insurance, with its attendant voluntary conscription of physicians will provide a continued tradition of caring for people as persons, improved availability, or lower costs.

Peer review, a lifetime habit for most of us, has been rendered more poignant with the development of Utilization Review Committees, and P.S.R.Os. Although quality assurance remains an avowed purpose of all review committees, it has become increasingly clear that the primary area monitored by government is cost containment. Admittedly, instances of over-utilization have been corrected, but hospital lengths of stay are finite and cannot continue to fall at a centrally conceived arbitrary rate without serious deficits in quality of care.

Most of us in the private sector have committed our professional lives to a goal of excellence and hard work, without primary concern for financial reward. Our current environment and forces that regulate it, have created many serous problems, not the least of which have been misconceptions about the relationship between learning and the process by which learning results in behavioral changes. Specifically, awareness of the need for cost-containment and the attendant threats of governmental agencies, magnified by the lay press, cannot and should not deprive patients of assured quality of care. No data are currently available that can show instances of governmental regulatory achievement insuring quality in the face of decreasing costs nor the dream of cost control and increasing productivity. Continued, active lobbying and the unconscionable costs embraced by the Veterans Administration are scandalous and not appropriate as a role model. Our own experience with Medicare has been a disaster.

Dollar-conscious government is alarmed by rising health costs. Our profession must be concerned with the attendant problems that relate to quality of care, and deficient or absent caring. Traditional practices have, through legislation, been disrupted. The outstanding accomplishments of clinics and ward services have been restrained, and the relationship between the practitioner and his patient who has fallen on bad times has been distorted.

The promises of Medicare and Medicaid have not, as espoused, offered better care to the elderly, or a more caring relationship to those who derived excellent care in free settings. Rather, it has disenfranchised a large proportion of sick and disabled, accustomed to high grade care, has facilitated money-grubbing at Medicaid mills, and has altered the time-honored practice of physicians in forgiving debts or modifying fees for their less fortunate patients.

Dollar economy has been achieved in the least humane fashion. The elderly, usually on fixed incomes, have been pushed out of hospitals into communities that are incapable for caring for still sick people. Home care is currently inadequately funded, and those essential elements of adequate transportation and cohesive, comprehensive caring are in their embryonal stages. This has rendered the elderly second-class citizens.

Despite the social pressures to which all of us are constantly exposed, where the profile of the physician has remained high but his image reduced, let us not lose sight of the observation that the collective intellect of government has to date failed to solve the myriad problems of an over-heated economy. We have found ourselves in a milieu of increasing hostility, criticized by government and self-appointed critics, obliged to beat our individual and collective breasts with HEALTH CARE the culprit.

It is altogether appropriate for the medical profession to react to further deprivation of care under the guise of cost containment. If government and its advisors will have their way, existing structures will tumble. There are, however, no guarantees that the new will be better than the old system. Rather, the young, talented, and caring student will question a system that precludes initiative, evokes sanctions, and denigrates the level of caring, which takes time and costs money. Second class students will become second class doctors and third rate teachers.

If we do not want our profession to become a headless cadre of medical care deliverers, responsive only to legislative directions, we must become increasingly vocal and verbal. We must attempt new experiments in alternative modes of health care delivery, specifically HMOS, and in particular independent physician associations. We must maintain dialogue with consumers and the corporate leadership who purchase health care. We must build stronger alliances with our hospital trustees and administrators, and develop comprehensive planning modes with experienced, private insurance corporations.

Decision-making must begin at the local level with the physicians' insistance upon quality assurance.

Our failure to become involved in social issues that affect our patients and the nation in which we live, bring no credit to the profession—and will eventuate in legislative efforts provoked in part, by default.

Health Care is a national issue; health caring is a commitment to which we must bend our collective advocacy.

Melville G. Magida, M.D.

*Stamford, CT*

## Podiatrists and Hospital Privileges

Included in this issue is an article on hospital privileges for podiatrists by Werner Strupp, J.D., general counsel for the American Podiatric Association. It involves not only orthopods, but entire hospital medical staffs because it is they who must make policy, and even consider changes in their medical staff bylaws. It does not express an opinion for or against such privileges for podiatrists, but is meant to keep our members informed.

Medical staffs and hospital boards of governors in our state increasingly will be receiving requests for hospital privileges by podiatrists. Some hospitals have already granted them, at least some privileges. The May and December 1978 issues of *Connecticut Medicine* contain several informative articles about podiatry, including an important federal legal case, the AMA position, the Connecticut law (P.A. No. 76-99) describing the statutory limits of podiatry, and the position of the Joint Commission on Accreditation of Hospitals.

Significant is the decision of the federal U.S. Court of Appeals, 5th Circuit,* one level below the Supreme Court, which ruled that a podiatrist has a constitutionally protected right to engage in his occupation and that, in public hospitals, "he is therefore entitled to a hearing conforming to minimal requirements of procedural due process of notice and an opportunity to be heard." It remanded the case back to the district court to insure he receive a procedurally fair hearing by the hospital. He had such a hearing, but was denied privileges on the ground that there was no need for podiatrists in the hospital because of an adequate supply of orthopedists. The district court upheld the hospital, but the podiatrist is now appealing his case to the same appeals court on the substantive issue—his right to practice his occupation in the hospital. This is still to be adjudicated.

The Texas case described by Strupp, also being appealed, is significant in that the legal grounds were not constitutional, but included "violation of civil rights, conspiracy, defamation, and invasion of privacy" by the hospital. The jury's verdict in favor of the podiatrist involved compensatory damages of $500,000 and punitive damages of $1 million against the hospital.

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*The Fifth Circuit includes, Georgia, Texas, Louisiana, Mississippi, Alabama, Florida and the Panama Canal Zone. The decision is legally binding on all states in this jurisdiction for the particular facts.

The extensive communication of the APA with the Federal Trade Commission described by Strupp is also significant. Its contention that the "activities of organized medical groups in denying podiatrists access to hospital represents an illegal restraint of trade" comes within the jurisdiction of the FTC and is something for medical staffs to be aware of. The FTC already has repeatedly stated that it is investigating the AMA, state societies, and county associations, as we in Connecticut know, for possible restraints of trade.

Though the article demonstrates a willingness and desire by the APA to negotiate its goals with the medical profession, it also expresses its determination to resort to the courts and to the FTC in defending what it considers its rights.

A Connecticut resolution to the AMA House of Delegates in June 1977 requested the AMA to update the Seldon Report on podiatric education, published in 1961, in order to keep medical staffs informed for evaluation of podiatrists. The Board of Trustees advised the House that it would not be appropriate for the AMA to evaluate colleges of podiatry, as it does medical schools, though an AMA committee has already found that there have been important advances in podiatric education and practice in the last few years. There is a liaison committee on podiatry of the AMA Board of Trustees, and recently it has instructed its commissioners to the Joint Commission on Accreditation of Hospitals to approve having podiatrists on committees of the Commission.

The AMA Board of Trustees "advises hospital medical staffs to evaluate the essentials of *each* [emphasis added] podiatrist who applies for privileges and to make recommendations on granting of practicing privileges in accordance with the individual's training, experience, and demonstrated competence and judgment."

It would seem that a blanket exclusion of all podiatrists as a class might be interpreted as antitrust. But even granting privileges does not necessarily mean to the limits prescribed by the law, no more than does a physicians's license entitle him legally to do unlimited hospital practice in all specialties of medicine and surgery.

Unfortunately we physicians must now look for possible legal complications in many situations we now encounter. The AMA is spending over $100,000 a month for litigation, mostly involving the FTC and chiropractors. An ounce of prevention based upon knowledge and legal advice is worth the trauma of even one suit.

Fred Fabro, M.D.

# Letters to the Editor

**Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.**

## A PLEA FOR COOPERATION

*To the Editor:* As a practicing internist, I would like to air a grievance that has long troubled me. I specifically refer to the practice of transferring patients to intermediate care facilities from the hospital service of surgical subspecialists and gynecologists. These patients are usually transferred to the nursing home with instruction that the patient's primary internist assume responsibility for the care of the patient.

The first time the internist becomes aware that the patient has been admitted to his service is when he receives a call from the nursing home, usually at night or on a weekend, requesting an admission physical and written orders. Occasionally, we are totally unaware that the transfer had taken place or that the patient had even been under the hospital care of a surgical subspecialist.

I am concerned about the unwillingness and inability of colleagues in orthopedics, gynecology, and surgery to continue to care for their patients after transfer to nursing homes, and who dump them on the unsuspecting hands of internists.

I am sure we internists would be willing to assume the burden of some of the care of these patients if prior consultation had taken place, but this is generally not the case. I am asking for greater sensitivity on the part of surgical subspecialists who are guilty of this practice.

Saul S. Milles, M.D., F.A.C.P.

*New Haven, CT*

## SIXTY-FIVE YEARS OF PUBLIC HEALTH

*To the Editor:* Recently, when I was asked about changes observed during some 65 years while participating in the so-called Modern Public Health Campaign, which dates from 1850 (or about 130 years ago) in the United States, I consulted diary notes. Surprising, perhaps, may be considered the number and significance of developments during the relatively short span of my involvement, as some of the following records suggest.

In the Connecticut State Public Health Laboratory on the Wesleyan University Campus, four of us, classed as bacteriologist-chemists, did all of the work aided by one "dishwasher".

Specimens from doctors, milk inspectors, water and sewage disposal plants, kept us busy, along with the clerical work and telephone reporting of positive diphtheria specimens. Dogs' heads for rabies, sputum for tuberculosis (the greatest killer), blood for syphilis from humans, for glanders from horses, for contagious abortion from cattle, gave us many positive findings in the 1914-1917 period, besides numerous specimens for diagnosis of gonorrhea, malaria, septic sore throat, typhoid fever, and more rare diseases. Industrial wastes were beginning to receive attention, as were wells, swimming pools, and food handling establishments. Drugs and poisons were seldom mentioned.

Only a few years previously, the Director of the Laboratory, Professor Herbert W. Conn, had been leader of the small group of "shoe leather epidemiologists", to trace the first typhoid epidemic, due to contaminated oysters, to the harbor source—milk borne disease control from drinking raw milk not pasteurized or boiled (even certified milk) was in its infancy. Herds of dairy cows were wiped out by bovine tuberculosis and by contagious abortion (brucellosis—undulant fever in humans), lead poisoning from water supplies and soda fountains was beginning to recieve attention.

Now, in 1979, diphtheria, the "deadly" disease of children before the 1922 campaign in New Haven, bovine tuberculosis, so often found among children and grandchildren of farmers and their friends' children before state-wide control of the disease in cattle, do not cause anxiety—nor does smallpox or typhoid fever, for example. Also where are the midwives of early days, and why?

Our greatly lowered disease and death rates tell only a part of the story.

Progress came with success, education, professional preparation, training, devoted volunteers, medical, dental, nursing, social service, health care, faith, hope, and money well spent.

Among my prayers are two, quite practical:

1. To remember that I do not have to discuss every issue or subject in a meeting or conference, even if sitting in the front row.
2. To accept with serenity the things I cannot change; courage to change the things I can; wisdom to know the difference.

CONNECTICUT MEDICINE is still a great help to many in many places. Early pages are worth reading even now, including the account of the New Haven meeting of the American Medical Association in those early days with a keynote address on "Sanitation."

Ira V. Hiscock, M.P.H., M.D., Sc.D.

*Chairman and Professor of Public Health, Emeritus,*
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## Disciplinary Actions Against Physicians Increase Six Fold in Six Years

In the past six years there has been a six-fold increase in state disciplinary actions against physicians, according to a survey conducted by the American Medical Association.

Much of this increase can be attributed to the steadily rising number of states providing immunity from civil liability for persons reporting errant physicians to state medical disciplinary agencies.

"Historically," said James H. Sammons, M.D., Executive Vice President of the AMA, "physicians who have reported colleagues to disciplinary boards have exposed themselves to the possibility of a suit for libel or slander. With more and more states granting immunity to people who in good faith report to state boards, the number of disciplinary actions which have been initiated have also increased."

The AMA study covered the years 1971 through 1977, and was participated in by 55 of the 60 state medical disciplinary boards. There are more than 50 state boards because some states have separate osteopathic boards.

Dr. Sammons pointed out that the study shows that in 1971, there were 119 actions, which revoked licenses, suspended narcotic permits, censured a physician, or denied license reciprocity from one state to another. In 1977, there were 685 such actions.

Because of the variety of disciplinary measures taken only those four actions were studied. In terms of total actions initiated against physicians, the number rose from 1,275 in 1971 to 3,662 in 1977.

It is important to note that these actions were all taken by state disciplinary boards. Organized medicine—the AMA or state or local medical societies—does not have the power to revoke or otherwise affect the license of a physician. The only types of disciplinary action a medical society can take are expulsion or suspension from membership, or censure, which do not affect a physician's ability to practice. Actual proceedings to revoke or otherwise affect a physician's licensure must be taken by the medical licensing boards of each state.

There are at the present time 14 states which have enacted legislation making it mandatory that physicians report evidence of professional malpractice to the state's medical disciplinary board. In eight states, medical societies are required to report instances of unprofessional conduct, 11 states require reporting by health-care facilities, and 11 states require reporting by insurers of malpractice awards or settlements. In each of those states immunity from civil lawsuits is granted to physicians, as well as others, reporting, in good faith, infractions.

The AMA study found that since 1971 the number of licenses revoked has risen from 45 nationally to 198. However, one of the problems in medical discipline has been the absence of a scale of disciplinary measures that would give a board the ability to impose a penalty other than license revocation or suspension.

In 1976, the AMA prepared model state legislation which created a broad range of flexible disciplinary actions, including outright revocation of a physician's license, suspension or limitation of license, submission to counseling or treatment, supervision of practice, requiring continuing medical education, and censure and reprimand. The AMA model legislation also provides for mandatory reporting to state boards physicians who are unqualified because of gross or repeated malpractice or professional incompetence. This model bill among its many other provisions also provides for the transfer of records to other agencies such as the licensing authorities of other states or hospitals. To date, 15 states have enacted all or parts of the AMA model legislation.

"By giving the licensing boards something more than the drastic measure of license revocation," says Dr. Sammons, "the AMA believes that more appropriate, more effective, and more frequently imposed discipline will result."

In the past several years, 35 states have enacted legislation to strengthen the licensing and disciplinary authority of state medical practice boards.

Other AMA initiatives include suggested legislation dealing with the physically and mentally impaired physician, which may result from alcohol or drug abuse or deterioration through aging. Thirty-one states have adopted all or part of the AMA Disabled Physician Act. In addition, 35 state societies have programs to identify and help rehabilitate impaired physicians.

Another interesting trend was revealed in response to questions in this AMA survey about the make-up of boards. Lay members are increasingly found in Medical Disciplinary Boards, a trend which began in 1973. In 1977, 27 boards had lay members.

—*New York State Journal of Medicine,* August 1979.

# Commemorative Issue in Honor of Hartford Hospital's 125th Anniversary

## First Priority: Keep Educating the Good Physician

Tomorrow's basic medical educational processes will be determined in large part by the kind of physicians then in demand and indications are that those physicians will be an organized group of people to a greater extent than they have been in the past.

Curricula and teaching technology will change certainly but no real upheaval in content, philosophy or methodology is likely. The fundamental nature of the medical training process involves the greater assumption of responsibility under the close supervision of a clinical faculty. To transmit the clinical experience the mentor must oversee the activities of the student in the process of the care of the patient. He cannot teach a physician without patients. And so, the teaching hospitals must continue to serve. As the academic health centers continue to become more highly specialized, tertiary care referral centers, they will become more imbalanced for the training of medical students and residents in preparation for the practice of medicine. Medical schools will develop affiliations with primary or secondary care hospitals in order to provide a more balanced view of medical care.

This may lead to the selection of a different kind of medical student, because certainly one of the attractions of medicine has been the opportunity for almost complete professional autonomy. That autonomy will become more limited. Professional accountability will be shared. Students coming to medical schools will be all ready prepared to accept that concept. The important point is that we will need to keep as our principal objective the making of a good physician, rather than a special kind of physician. The amount of knowledge available for assimilation is expanding. The possibilities for exposure to different career paths are increasing, along with the demands made on the profession. It is unlikely therefore that every school will be able to provide every kind of experience.

"Electives" have become a significant part of the curriculum. Through the mechanism of the electives some degree of experience broadening can be matched to the particular interest of the individual student. The elective must not become a device for undermining the preparation of the individual as a sound physician, however. Particularly at a time when the profession is in the public fishbowl, the traditional curriculum is questioned. Some claim that it is the curriculum which is at the heart of the problems with health care in America; too much emphasis on science, too much on specialization, too much on technology, and not enough concern for primary and holistic care, not enough sociology and ethics.

Cost of hospital care will escalate considerably in the next few decades because we mostly will be hospitalizing acutely ill patients in intensive care beds. This will result in much improved, better financed ambulatory care services and could help the medical schools if there is no discrimination against teaching institutions in reimbursement for patient fees or physician services. On the other hand if the medical school teaching hospitals are to be treated under cost containment legislation exactly the same as our community hospitals without teaching programs, then medical centers which own their own hospitals are going to be in severe difficulty.

The impact of national health insurance upon future medical education is unknown because the form it will take is unpredictable. Should it be a gradually expanding system that emphasizes demand services beyond the prepaid basis, it may enhance the fiscal position of medical schools. But if it provides no mechanism for supporting the educational component of medical schools (the training of students, interns, and resident), these schools will be unable to offer competitive prepaid health care programs.

There is no board of directors for health except for Congress. As a federally funded activity, health research is paid for by society. As health costs have increased and taken a larger part of the federal budget, funding of research to discover the causes of disease has diminished relatively and absolutely. Twenty years down the road we will have an inadequate science base to support research for a modern health care system from a lack of investment now.

This will reflect itself in a diminshed vitality in our basic science departments and the quality of research being done in the medical schools. And this, in turn could well have an impact on the kind of physician we produce in the TWENTY-FIRST CENTURY.

Michael A. Rossi, M.D., Guest Editor

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# The Founding Staff of Hartford Hospital and Its Legacy

H. DAVID CROMBIE, JR., M.D.

Progress in medicine represents such a subtle continuum that it may be artificial to create a "stop-action" image of any particular year of decade as is so often appropriate to political history. Yet, biographical sketches constructed by a retrospective glance over 125 years demand a contemporary frame of reference to measure and enhance the image of their subjects. Mid-nineteenth century Hartford was home to about 18,000 people increasing particularly at that time by an influx of Irish immigrants. Manufacturing and casualty insurance was established in the city as was Samuel Colt's firearms manufactory in the South Meadows. Railroad and river travel flourished. Hartford's streets were wide but unpaved with local travel by horse-drawn vehicle. Lighting was by gas, heating by coal or wood. The venerable Hartford Courant (1764) kept the populace informed and among today's institutions the Deaf and Dumb Asylum (1819), the Retreat for Insane (1822), and Trinity College (1824) were already landmarks in the city. The Hartford (City) Medical Society was of recent vintage, founded in 1846.

The medical care of the inhabitants of Hartford was provided by a handful of physicians, generalists to be sure, but with special interests and skills reflected by the character of their caseload. Some emphasized operative work; others, obstetrics; others, general medicine. Office hours were short in comparison to time spent on visits in a one-horse "chaise" in the city or "sulky" in rural areas. On his visits the physician encountered pneumonia and pleurisy for which bleeding was still the popular treatment in the 1850's. Smallpox vaccination was a well-entrenched practice. Typhus and typhoid fever were common and were distinguishable as separate entities after 1837. Tuberculosis, the white plague, was widespread and increasing as a lethal scourge, treated by open air exposure, whiskey, and occasionally by venesection. Yellow fever, so devastating to the world's armies at mid-century, and malaria prevailed with the relationship to swampy, damp surroundings established, but with no hint of the role of Anopheles or Culex. There were 2500 deaths in Hartford in 1854, one-third under the age of five years, another third from five to forty years. Fractures, burns, scalds, dysentery were commonplace. The pharmacopeia included laudanum (opium), antimony, tartar emetic, mercury, herbs, seeds, and their various concoctions for symptomatic relief.

Dr. Horace Wells of Hartford led the conversion from surgery under Jamaican Rum to the humane realm of "anesthesia" by nitrous oxide and ether. Amputations, occasional gastrotomy (laparotomy), ovariotomy, and cutting for stone were practiced by surgeons operating in the home of the patient. Handwashing was performed after surgery rather than before and balsam of Peru was the nearest thing to an antiseptic. Laudable pus was still laudable. Into this medical community the Hartford Hospital, with its founding staff of six physicians, was given birth.

At a meeting of the Hartford Medical Society on January 20, 1851, Drs. G. W. Russell, E. K. Hunt, and M. W. Wilson were appointed to investigate what "additional accommodations might be needed for the sick and poor of this city." Progress was slow until the boiler explosion at the Fales and Gray Car Manufactory on March 2, 1854 resulted in nineteen deaths and twenty-three injured. By May, 1854, a charter of incorporation of Hartford Hospital had been granted by the State Legislature and directors were promptly selected. The directors appealed to the Hartford Medical Society in 1855 to nominate six of its members as the first medical staff of Hartford Hospital. Drs. Beresford, Russell, Hawley, Hunt, Wilson, and Barrows were chosen. Dr. Myron W. Wilson's death at age 37 in 1855 led to the nomination

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Excerpts from paper presented at the meeting of Beaumont Medical Club, New Haven, CT, December 12, 1979.

of Dr. David Crary to fill his place. The cornerstone was laid in 1857, the dedication ceremonies were held in April, 1859, and the first patient, Frederick Moore, admitted on August 1, 1860, under the care of a medical staff comprised of Samuel B. Beresford, M.D. (1806-1873); George B. Hawley, M.D. (1812-1883); Ashbel W. Barrows, M.D. (1816-1896); David Crary, M.D. (1806-1894); Ebenezer K. Hunt, M.D. (1810-1889) Gurdon W. Russell, M.D. (1815-1909).

One might conclude that the Hartford Medical Society of 1855 took its mandate quite seriously in selecting the first medical staff for Hartford Hospital. The leaders of the society were determined that the institution be the best possible for the city and the state; thus, it must be started with the best people. They obviously wished to establish a distinguished patient care institution that would receive initial community support and of which the community would be forever proud. What better way than to choose sound, leading physicians, established in the city, with solid medical training gleaned from the best surgical minds of Edinburgh and the medical elite of New Haven and Philadelphia. Their chosen appointees possessed interests ranging from the technical to the scholarly, from the historical to the humanistic to the organizational needs of the profession. They brought personal wealth, from which they gave generously to the institution during life and thereafter, a clear benefit and example to the populace in the early fund-raising days. Their positions in the fledgling life insurance business were meaningful in appeals to the business community. All but Barrows were founding members of the Hartford Medical Society, which was certainly no disadvantage in cementing relations between Hartford's physicians and the new hospital. Most of all they were active practitioners, leaders among their peers, imbued with a great sense of purpose.

But who could have known that the average lifespan of the six would be just short of eighty years, with all continuing their active encouragement of the hospital to their final years? Who could have known that four of the six were to be elected to the Presidency of the Connecticut Medical Society, bringing further honor to themselves and their beloved hospital? Call it prescience, call it wisdom, call it success.

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# Medical Education at Hartford Hospital: An Historical Review

MARJORIE BINGHAM

The mission of Hartford Hospital as an institution dedicated to patient care and education began with a modest medical staff of six physicians. In the early years they and their successors shared, on a rotating schedule, the management of patients who did not have their own physicians. Serving the needs of a growing patient population on a 24-hour basis became increasingly difficult during the first decade of operation. In order to utilize their resources more effectively, the innovative medical staff decided to recruit a graduating medical student who would live on the premises. His services, in turn, would be appropriately compensated by practical instruction at the bedside. From this pragmatic experiment evolved the concept of preceptorship training as a vital component of patient care. By extending their role as practitioners to educators, the medical staff formed the foundation for clinical medical education.

In 1866 Hartford Hospital began to train physicians as potential members of its medical staff with the appointment of Dr. Charles Goodyear. As House Physician, he resided in the hospital and was responsible for providing 24-hour coverage of all patients who at that time were located on two combined medical-surgical wards. At times, the duties

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were heavy and confining but the assumption was made that acquisition of clinical experience amply repaid him for his labors. For faithful performance and fulfillment of the one year term, the intern received $50. A diploma was not awarded until 1899.

Six years later a new wing was added which allowed for separation of the expanding medical and surgical services. The burden of supervising four wards was shared by the addition of a House Surgeon. His duties were defined in general terms and extended from admissions to management of the patient's record.

By 1881, differentiation of training levels was indicated in the hospital rules governing Resident and Assistant Resident Medical Staff. The first six months were served as an assistant and the remainder of the term as resident. In 1889 the term increased to 18 months when two more interns were added. In 1891 the training period at each level was extended to one year. A written agreement was required in which the intern accepted conformity to a long list of rules and regulations. It emphasized the importance of availability in rather emphatic terms.

The comprehensive list of duties included bedside rounds, reports, emergencies, prescriptions, diets, chart-recording and reporting of improper conduct on the wards. The graphic style in which they were written seems to illustrate the "indentured servant" status of the intern in those early years.

By 1902, there were six interns, ranging from first and second assistant to resident physician and surgeon levels, who covered the medical, surgical, pediatric and obstetrical wards. Ample clinical education was provided by these services which consisted entirely of ward patients until 1906. Formal didactic teaching was minimal, but the academic interests of the visiting staff were instrumental in the initiation of a medical-surgical journal club in 1909. In that year Edward A. Deming was listed in the Annual Report as Assistant House Surgeon. In the 1910 Report Julian L. Birdsong was recorded as House Gynecologist and Arthur Heublein, Roentgenologist. Between 1912 and 1917, the list of names included Clinton Deming, Eliot S. Gogswell, Carl Vernlund, Freeman Clason, Stanley Weld, Bernard Spillane, and Hartwell G. Thompson. Like their predecessors and successors, they joined the Medical or Visiting Staff following their internship not only as practitioners but educators as well.

Until 1917 all anesthetics were administered by the interns. In 1918 the first House Dental Surgeon was added to the list of specialized preceptees which included House Physicians, Surgeons, Obstetrician-Gynecologist, and Pediatrist. The rather simplistic approach to specialty training developed out of the special professional services that were provided on the designated specialty units. By 1919, the private service had grown large enough to require the assignment of a house officer. The intern was G. Gardiner Russell. Also, in that year House Staff began assisting Visiting Staff in the instruction of nursing students in the Hartford Hospital Training School.

At the close of this 54-year period most of the Visiting Staff was composed of Hartford Hospital graduates. The 1866 commitment to clinical training of future practitioners had reaped its rewards.

In the post-World war I years the Visiting Staff was enriched by the addition of physicians who trained at centers outside Hartford. New ideas of medical education were brought to Hartford Hospital chiefly by physicians from Baltimore, Chicago and New York. In 1925 the appointment of a full-time pathologist-bacteriologist, Dr. Wilmar M. Allen, added a new dimension to the education program and morbidity and mortality reviews were introduced. In 1930 the House Staff increased to 18 interns. Two years later, a recognized specialist in radium treatment, Dr. Gilbert Heublein, developed a Radiology department.

During the thirties it was such individuals as Drs. Donald Wells, James Fox Jr., G. Gardiner Russell, Sidney Quarrier, Wilmar Allen and Ralph Kendall, specialists in internal medicine, surgery, and pathology, who shared in the development of a comprehensive teaching program for the two-year internship. This included daily ward rounds, weekly surgical tumor conferences and CPC's, monthly Journal Clubs, educational films, a weekly guest speaker program and noon conferences often shared by the house staff and medical staff. In addition, they encouraged expansion of the services of the Medical Library. By 1935, 24 interns were being trained in the two-year program. The following year the first Director of Anesthesiology was appointed. In 1937, Dr. Ralph Tovell inaugurated the first residency program—a two-year residency in anesthesiology. The development of twelve specialty examining boards provided the incentive to establish more formal training programs.

In 1940 the first Pathology Intern and the first Resident in Neurology-Neurosurgery were added to the growing list of specialized traineeships. Two years later an Internist from the Pratt Diagnostic Clinic, Dr. John C. Leonard, was appointed Assistant Medical Director and Secretary of the Intern Committee. He developed the New Ward Admission Clinic which was later known as the Diagnostic Clinic, the first of many organized teaching clinics to augment the educational resources for house staff training.

In the forties the disruptive influence of the draft and federal wartime regulations created the temporary demise of the two-year internship program. In the dark days of 1943 the staff of 24 interns was reduced to 12 in a 750-bed hospital. With the support of the Intern Committee Dr. Leonard developed an accelerated nine-month internship program called the 9-9-9 plan. Some of the interns were fortunate enough to remain for a second nine-month training period. An even smaller number were retained for nine additional months since the hospital was able to offer residency-level training. The concept of the junior residency year in either medicine or surgery was developing response to a wartime emergency. The experiment of the 1942-1945 era was a successful demonstration of what could be accomplished by an internist from another medical center who had been appointed to the administrative staff without a circumscribed role in the graduate education of physicians. It also illustrated the fact that a full-time educator could be more effective than the combined efforts of the Intern Committee in defining the requirements and obtaining the resources needed in a teaching hospital. An invaluable financial resource for medical education was the Hartford Hospital Association which had been organized in 1944. For over a decade it supported the Hartford Hospital Bulletin, the Guest Speaker Program, and the House Staff stipend. The experiences of this critical period provided an opportunity for Dr. Leonard to define the role of a Director of Medical Education. When Dr. Leonard left the hospital in 1945 to become Director of the Pratt Diagnostic Clinic at the end of this critical period, Dr. James Fox was appointed Assistant Medical Director to continue direction of the medical education program.

The dual role of training some physicians for general practice and others for specialty Board certification was fully developed by 1946. At that time there were residency programs in nine departments —Anesthesiology, Neurosurgery, Radiology, Pathology, Internal Medicine, Surgery, Pediatrics, Obstetrics and Gynecology and Orthopedics. Many of these residencies included affiliations with university or specialty hospitals such as Yale, Newington Children's Hospital, the State T.B. Hospital at Uncas, and Memorial Hospital, New York City. The commitment of the Medical and Administrative Staff to an organized educational program designed for potential generalists and specialists who might practice in the community or assume a leadership role within the hospital was well established.

In 1947, Dr. John Leonard was invited by the Medical Staff and Administration to return to Hartford Hospital as the first full-time Director of Medical Education in the country. He was the author of the classic description of the DME position which eventually was circulated in several national medical journals. When an increasing number of community hospitals appointed DMEs, Dr. Leonard organized a national Directors of Medical Education Association which, in later years, developed a membership of over 300. Today it is known as the Association of Hospital Medical Educators which in abbreviated form is pronounced "ah-me." Ongoing written and verbal communication with potential and newly appointed DMEs as well as with educators at the medical centers and leaders in the national organizations concerned with graduate education placed Hartford Hospital in the forefront as a non-university teaching hospital.

Voluntary directorship of departmental programs was becoming increasingly difficult as the number of residency positions expanded. The need for fulltime leadership in the major clinical disciplines became apparent. In 1963, Dr. Ralph Reinfrank terminated his position as Director of the Outpatient Department and became Director of the Department of Medicine. This was the first fulltime directorship of a clinical department. The decentralization of leadership for interpretation, evaluation and modification of educational policy could no longer be assumed primarily by the DME. At the national level the number of rotating internships was decreasing as specialty internships were increasing in community hospitals. Fully specialized programs for the entire graduate education period had been supported by the academic centers for several years. At the time of Dr. Leonard's death in April, 1966, specialty internship programs were being considered by the Departments of Medicine and Pediatrics. The abrupt termination of 19 years of commitment to one man's leadership and the interaction of divergent educational philosophies regarding medical education created an atmosphere of uncertainty. What educational direction should be adopted and how it would be organized and integrated required redefinition in terms of an emerging medical school and adherence to the AMA and specialty board policy changes.

Between 1967 and 1968, the hospital's long investment in medical education was undergoing a reassessment of its mission in relation to projected local and national developments. An ad-hoc education committee consisting of representatives from the Board, Administration, and Staff was delegated the responsibility of establishing an effective framework which would allow for facilitation of the hospital's total educational goals. The committee's recommendation emphasized the importance of a unified educational policy and coordination of all educational activities. It was agreed that this would be facilitated most effectively by the organization of a Department of Education under the directorship of a physician who would be attuned to the needs of the Administration and the Medical Staff.

In June 1969 Dr. John G. Freymann was appointed Director of Education. His multifaceted role might be described as that of an advocate who would anticipate national and regional trends and recommend, facilitate, and integrate educational policy.

A full-time teaching faculty was rapidly forming along departmental lines with a growing ability to offer a more uniformly structured educational experience. This included the addition of two Directors—Dr. James Foster in Surgery and Dr. R. Clay Burchell in Obstetrics and Gynecology. In 1967, one-year, John C. Leonard teaching scholarships were initiated to broaden our voluntary teaching faculty resources by attracting new subspecialty trained physicians to the Medical Staff. Subspecialty internships in Medicine, Pathology, Pediatrics and Surgery were initiated. In response to the increasing popularity of the specialty programs, eight rotating internship positions were eliminated. The number of House Staff positions increased 95 to 117. During this period the Department of Medical Education had evolved into an advisory and coordinating office for policy and operational decisions of the various educational programs. The emphasis program specialization and departmental management of the entire graduate education period fostered decentralization of educational leadership.

During Dr. Freymann's five-year directorship a substantial number of changes occurred in medical education. In 1971 a pediatric cardiologist, Dr. Leon Chameides, was appointed full-time Director of the Department of Pediatrics. He replaced Dr. Frederick Flynn whose administrative responsibilities had been divided between Hartford and Newington Children's Hospital. A year later, the Department of Psychiatry appointed its first full-time Director, Dr. Donald L. Brown. Between 1970 and 1972, affiliated residencies in otolaryngology, ophthalmology, orthopedics, psychiatry, and urology were initiated with the University of Connecticut Health Center. In 1970 Hartford Hospital inaugurated a three-year Oral Surgery Program and the Department of Medicine obtained approval for a two-year Fellowship in Cardiology. A year later the Department of Medicine initiated fellowship level training in Gastroenterology as a joint program with Yale. In 1973 fellowship training in infectious disease was introduced. During that year the modified Rotating Internship was expanded to twelve positions and was renamed the Flexible Year in 1974. In order to fulfill the new AMA regulations regarding elimination of the free-standing internship in 1975, the content of the program was restructured. By limiting clinical rotation requirements to six months and allowing for selective and elective assignment options this program could be linked to the continuum of medical education from the first to the last postgraduate year. At the conclusion of Dr. Freymann's directorship, affiliation agreements had been approved for the July 1975 commencement of University-sponsored programs in family medicine and pediatrics and plans were being developed for a five-year University-integrated program in surgery within the same year.

Within the 1969-74 period, the number of house staff increased from 117 to 159. In 1974 Hartford Hospital sponsored ten programs and participated in eight University-affiliated programs which included two at the fellowship level. One hundred and eighty-seven interns and residents were processed for educational assignments during that year. The hospital's commitment to medical education at the graduate and undergraduate levels required expansion of its educational facilities and services. One of the major accomplishments was the opening of the new medical library in 1974. It quadrupled the space of the old library and provided new services such as computerized bibliographic searches and audio-visual carrels for self-instruction. Floor Reference Centers for medicine, surgery and pediatrics were developed and eight additional specialty unit centers were projected. Clinical librarians were added to the patient care teams in medicine, surgery, pediatrics and psychiatry to provide valuable resource information relevant to specific clinical problems.

At the termination of Dr. Freymann's directorship in 1974, it was evident that the hospital's investment in medical education had changed considerably. The hospital had become a major locus for medical student education as well as a center for eighteen specialty programs extending from internship to the fellowship level. While the independent programs expanded, University-affiliated programs were added. The impact of non-hospital-based programs and the introduction of clinical education for medical students required an entirely different level of educational identification and policy coordination. Involvement in sharing our educational and clinical resources with a developing academic center had increased significantly. Therefore, the collaborative efforts of the program directors were critical in assuring that the hospital and the University goals and objectives were complementary. The development of professional knowledge and skills unique to each specialty and appropriate to each educational level required not only effective planning but rational negotiation. These were some of the primary challenges of medical education during this period.

# Experience in the Treatment of Acute Leukemia Hartford Hospital: 1970-1978

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We have reviewed our experience with 133 patients diagnosed at Hartford Hospital between 1970 and 1978 with acute non-lymphatic leukemia (ANLL) and acute lymphocytic leukemia (ALL). The complete remission rate (CR) for 80 cases of ANLL treated with the "L6," "L12," or "L14" protocols was 50%. Remission induction was 61.8% in the group less than 50 years old and 41% in the older group. Two-year survival of complete responders in either groups was similarly 37.5%. The complete remission rate for 18 adult patients with ALL treated with the "L10" protocol was 83% with a median survival of 36 months. A small group (10 patients) with ANLL who presented with a dysmyelopoietic syndrome were treated with the "L6" or "L12" protocol. Three of these patients achieved complete remission. These results are comparable to those of major research institutions.

## Introduction

In the past eight years, dramatic improvement has been made in the care and survival of adult patients with acute lymphatic leukemia (ALL)[1,2,3,4] and acute non-lymphatic leukemia (ANLL).[3,5,6,7,8,9] Success has been attributed to improved chemotherapeutic protocols, better supportive care with platelet and granulocyte transfusion, and intensive use of antibiotics during the induction phase. Most authorities stress that patients be treated in institutions capable of providing this supportive care.

We have reviewed the experience in our private practice of hematology in the treatment of adult acute leukemia at the Hartford Hospital in order to compare the results with the reports of major investigational centers. We also report on a large separate group of patients with dysmyelopoietic syndromes (DMS) whom we followed for months to several years until they became frankly leukemic. This group of patients is often excluded from investigational protocols in acute leukemia because they have a worse prognosis than acute leukemia presenting de novo.[2,7,9]

## Materials and Methods

The records of all adult patients with acute leukemia at Hartford Hospital from January 1970 to November 1978 were reviewed. Only patients treated by the authors (DK, AK, PD) were selected for analysis. Information obtained from the Hospital records was supplemented with data from office records. One hundred and thirty-three patients were treated representing 90% of all adult acute leukemics diagnosed at Hartford Hospital during this period. No patient had been treated previously for acute leukemia. Classification by type of leukemia was achieved by standard morphologic criteria from Wright stain peripheral smears and bone marrow aspirates and in most cases since 1977, correlated with special histochemical stains (PAS, peroxidase, Sudan black, and esterase stains). Recently a review

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committee of three hematopathologists blindly re-classified all these cases according to the French-American-British (FAB) criteria.[10] The diagnosis reported here are expressed in the conventional manner as the re-classification did not show significant survival trends.

The patients with ANLL were treated with cytosine arabinoside and thioguanine according to protocols in use at Memorial Sloan-Kettering Hospital in New York City. Through 1975, patients were treated with the "L6" protocol[7] consisting of twice-daily doses of cytosine arabinoside and thioguanine for a variable period until an M1 marrow was achieved. Patients were then given a complicated consolidation and maintenance therapy schedule. From 1975 to 1978 the patients were treated with an "L12" protocol which differs in its more complex consolidation regimen (unpublished data). In 1978 patients were treated with the "L14" protocol which includes continuous 24-hour infusions of cytosine arabinoside, oral 6-thioguanine, and daunorubicin (or doxorubicin) for three days during the induction followed by a one year intensive consolidation of chemotherapy and then no maintenance (unpublished data). Finally some patients were not treated because of age and concurrent debilitating disease.

Eighteen adult patients with ALL, ages 13-67, were initially treated with either the Memorial Sloan-Kettering "L2" protocol[3] or the "L10" protocol[1] which incorporates long term intrathecal methotrexate instillation. St. Jude's protocol for childhood ALL was used in one case.[11]

Twenty-one patients presented initially with DMS, usually as a refractory anemia with excess of myeloblasts or chronic myelomonocytic leukemia.[12] [13] All of these patients were followed and supported with transfusion therapy alone until a clear-cut evolution of acute leukemia occurred. All of these patients developed ANLL; there were 12 acute granulocytic leukemias, 5 acute myelomonocytic leukemias, 2 acute undifferentiated leukemias, and 2 erythroleukemias. Ten patients were treated aggressively with the "L6" or "L12" protocols and 11 patients were not treated or treated conservatively with single agent chemotherapy as 6 mercaptopurine. Since these patients who initially present with DMS have an altered prognosis[9] [13] than the larger group presenting with de novo leukemia, they are separated in this report. All DMS patients, except two patients with preceding Hodgkin's disease, were over 50-years-old (mean age 69 years). No attempt was made to assess the number of patients who were followed with a DMS that did not evolve into acute leukemia at the time of this report.

Response to chemotherapy was classified as complete remission (CR), partial remission (PR), or no response (NR). Complete remission was defined as less than 5% blasts in the bone marrow, hemoglobin greater than 10 gms/ml, white count greater than 3,000 per cubic mm, platelet count greater than 100,000 per cubic mm, and no blasts in the peripheral smear, and a normal physical exam. Failure to obtain all of the above led to the classification of partial remission and failure to meet any of the criteria was called NR. All patients, regardless whether death occurred early in treatment, are included in this analysis.

Survival time and durations of remission are expressed in months from the date of diagnosis unless otherwise stated. Statistical tests used to determine differences between various parameters or groups of patients with the Chi squared test and the Wilcoxan sign rank test.

## Results

One hundred thirty-three adult patients with ANLL or ALL were seen between January, 1970 and November, 1978 (Table 1). Ninety-four patients presented with de novo ANLL, but 14 of these were not treated with combination chemotherapy because of concurrent debilitating diseases not related to leukemia. Of the 80 patients treated with aggressive chemotherapy, 40 had acute granulocytic leukemia, 27 had acute myelomonocytic, 5 had acute monocytic leukemia, and 5 had acute undifferentiated leukemia, 2 had erythroleukemia and 1 had acute progranulocytic leukemia. The mean and median ages of these patients were 51 and 55 years respectively. Fifty percent of these 80 patients achieved complete remission, the median survival of patients achieving complete remission was 18 months with a mean of 21.5 months. The median duration of complete remission was 11.0 months (with a mean of 14.6+ months).

Of the 34 patients who were less than 50 years old (mean age 31 years), 21 (61.8%) achieved complete remission (Table 2). The median duration of complete remission was 11.5 months (mean 14.9+ months) and the median survival of complete responders was 18.0 months. Forty-six patients were greater than 50 years old on presentation (mean age 67 years) and 41.3 achieved complete remission, a significantly lower

Table 1

108 CASES OF ACUTE LEUKEMIA:
CLASSIFICATION AND RESPONSE TO THERAPY

| | *No.* | *No. of CR (%)* | *Median survival of complete responders, months* |
|---|---|---|---|
| 1. ANLL | 80 | 40 (50) | 18.0 |
| 2. ANLL-preceded by DMS | 10 | 3 (30) | 9.0 |
| 3. ALL | 18 | 15 (83) | 34+ |

Table 2

RESPONSE TO TREATMENT AND SURVIVAL IN ANLL IN 2 AGE GROUPS

| | *<50 years* | *>50 years* | *All ages* |
|---|---|---|---|
| No. | 34 | 46 | 80 |
| CR, No. (%) | 21 (62) | 19 (41) | 40 (50) |
| Median duration of CR, months | 11.5 | 11.5 | 11.0 |
| Median survival of complete responders, months | 18.0 | 19.0 | 18.0 |
| Median survival, all patients, months | 11.0 | 7.0 | 7.0 |
| 2-year survival of complete responders, % | 33.3 | 42.0 | 37.5 |
| 3-year survival of complete responders, % | 9.5 | 15.8 | 12.5 |

percentage than the younger patients ($p < 0.05$). The median duration of complete remission in this older group however was 11.5 months with a mean of 18.2 months and the median survival of the complete responders was 19 months (mean 22.5+ months). There was no statistically significant difference in the survival of complete responders in either age group (Table 2). There is highly significant difference between survival of complete responders and partial or non-responders ($p < 0.01$) in both age groups.

Seven of 21 (33%) complete responders in the younger age group had 2-year survival. Two patients (9.5%) are alive and in remission at 3 years. In the older age groups, 8 of 19 complete responders (42%) survived longer than 2 years. And 3 (15.8%) were alive at 3 years. At this time 8 patients are surviving at 7, 9, 10, 17, 22, 24, 88, and 104 months from diagnosis, and all but the 17-month survivor are in complete remission.

The complete remission rates for the various types of ANLL were not significantly different: they were AGL 54%, AMML 41%, AMOL 50%, AUL 50%, erythroleukemia 50%, and 1 patient with progranulocytic leukemia at 0%.

Twenty-one patients with the dysmyelopoietic syndrome (DMS) eventually developed ANLL. The time interval from the diagnosis of DMS to acute leukemia ranged from 2-30 months with a mean of 8.3 months. Median age of these patients was 69 years (with a mean of 67.3). In many of these patients, underlying debility and concurrent illnesses precluded aggressive chemotherapy, but 10 of these patients were selected for treatment with the "L6" protocol (Table 3). Thirty percent (3 patients) achieved complete remission and 4 were partial responders to this chemotherapy. The median duration of complete remission was 5 months with a mean of 12.3 months. Median survival of complete responders was 9 months from the onset of therapy and 18 months from the onset of the DMS. Median survival of the treated group (10 patients) was 4.5 months from the onset of therapy and 19 months from the onset of DMS. Median survival of the untreated patients was 1 month from the onset of acute leukemia and 8 months from the diagnosis of DMS.

Among a total of 115 patients with ANLL (including de novo and dysmyelopoietic patients) 12 presented with the preceding diagnosis of another malignancy. Three patients had Hodgkin's disease previously treated with combined modality therapy and 1 with chemotherapy only, 1 patient had non-Hodgkin's lymphoma, 1 renal cell carcinoma, 1 ovarian carcinoma, 1 patient multiple myeloma. All of these patients had been treated with alkylating agents. Five patients with either breast cancer, lung or colon cancer had not received prior chemotherapy. Of these 12 patients, 5 were treated aggressively with only 1 complete remission in a patient with breast cancer who had not received prior chemotherapy. The median survival of this group was 2 months.

Eighteen patients with ALL, ages 13-67 (mean age 37), were treated with the "L2," "L10," or St. Jude's protocol (1 patient). Fifteen patients (84%) achieved complete remission (Table 1). Median duration of the 1st complete remission was 31.5 months (with a mean of 26.8 months). Seven patients relapsed but 4 of the 7 were successfully reinduced to complete remission. Median survival of patients achieving complete remission has not yet been reached but will be in excess of 36 months. Median survival of the entire group will be in excess of 33.5 months. Seven patients are alive and in complete remission at 28, 34, 34, 36, 44, 56, and 73 months. Two additional patients are alive but currently relapsing at 17 and 46 months

Table 3

PATIENTS WITH ANLL PRECEDED BY DMS, RESULTS OF TREATMENT

| | *No.* | *Median time to evolve to ANLL, months* | *CR No. (%)* | *Median survival of complete responders, months* | *Median survival from DMS, months* | *Median survival from ANLL, months* |
|---|---|---|---|---|---|---|
| Treated | 10 | 8.5 | 3 (30) | 9.0 | 19.0 | 4.5 |
| Not treated | 11 | 5.0 | 0 | — | 8.0 | 1 |

of complete remission. Two patients who achieved initial complete remission died suddenly in complete remission with massive G.I. bleeding and intracerebral hemorrhage at 1.5 and 2 months as complications of intensive chemotherapy.

## Discussion

We have reported a large series of adult acute leukemia collected in a single large community hospital and treated in a similar fashion by a small group of hematologists.

In the past 10 years, therapy for acute nonlymphatic leukemia and adult acute lymphatic leukemia has dramatically improved. There has been a progressive increase in remission induction rates from initial lows from 15-20% until now the achievable rates of 60-70%.[9] In association with the increasing percent remission induction, there has been an increasing percentage of long-term survivors. We have demonstrated comparable degree of remission induction and long survivors in both our ANLL and ALL series.

In 1975 Clarkson et al.[7] reported their experience using the "L6" protocol at the Sloan-Kettering Hospital with acute de novo ANLL. In this series (mean age 45 years), the complete remission rate of 56%, median remission duration 10 months and median survival of responders was 2 years. Our experience using essentially the same protocol is an overall complete response rate of 50% with a median duration of complete remission of 11 months and a median survival of 18 months in a complete responder group. The Memorial study showed an 18% 2-year survival rate of complete remission patients and we were able to demonstrate 37.5% 2-year survival in our complete remission group.

Grann et al,[14] using the Memorial-Sloan Kettering "L6" protocol reported a series of 93 with ANLL (all over 50 years old) treated at Yale New Haven Hospital, Sloan-Kettering, and 6 Connecticut community hospitals. They too found no difference in remission rate or survival between the special centers or the community hospitals, and obtained a 44% complete remission rate with the median survival of responders at 19 months and a 40% 2-year survival of complete responders.

These studies may be contrasted to the multi institutional study of community hospitals reported by Erck et al. from Rochester, New York.[15] In the study of 187 patients with ANLL, they reported an overall response rate of 24% in the total series, but a 42% complete remission rate in 98 patients treated with cytosine arabinoside and thioguanine protocol. However, the median survival of 12.5 months in the complete responder group represented only 7.5% of the total cases of ANLL.

As chemotherapy induction protocols have improved, we now use a 3-day induction with either doxorubicin or daunorubicin in addition to a 7-day infusion of cytosine arabinoside with or without 6 thioguanine. We anticipate that the remission induction rate in the new younger ANLL patients will approach 70%.

Our finding of a lower response rate in older patients is similar to the findings of other investigators.[5 15 16] Peterson and Bloomfield[16] achieved a 30% complete remission induction with a median survival of 14+ months in patients over 60 years. They found that, once complete remission was induced, there was no difference in the proportion of 2-year survivals or duration of complete remission between the older and younger groups. Bennett et al. reported a 20% complete remission rate in patients over 60 years old in a recent ECOG series[5] using an induction regimen of vincristine, cytosine arabinoside, 6 thioguanine and daunorubicin. This is contrasted with the recent series of Gale[17] who achieved an 82% complete remission induction in patients over 60 using cytosine arabinoside, 6 thioguanine and daunorubicin. The majority of reports analyzing patients in the past 2 years have showed a consistent 60-70% rate of complete remission in all age groups using the induction regimen which includes an anthracycline antibiotic doxorubicin or daunorubicin.

We found no differences in response rate or survival in the various subtypes of ANLL. Foon et al.[18] could not correlate subclasses of ANLL and response to chemotherapy, remission duration, or survival in a series of patients classified with the FAB system.

The group of patients who were first diagnosed to have DMS and later developed frank leukemia constitute an interesting subgroup of acute leukemia. Many authors have reported that these patients with smoldering leukemia, subacute granulocytic leukemia or chronic monomyelocytic leukemia had a poor prognosis upon developing acute leukemia.[2 7 9 19] Our results confirm these findings; however, there was a small number of selected patients in this category who obtained complete remission. The rate of complete remission and overall survival of this group was not significantly different from a group of elderly patients with acute de novo non-lymphatic leukemia. Median age of both groups was 67 years which makes this comparison valid. The aggressively treated patients with DMS had a 30% complete remission rate and median survival of 9 months with a mean of 15 months from the onset of chemotherapy. Aggressive treatment in patients with DMS should be avoided for this treatment often causes excessive morbidity and mortality.[9 13] Yet when fulminant leukemia develops, treatment in selected patients is indicated. By carefully following the patients and withholding treatment until the appropriate time, survival can be prolonged in the entire group.

Patients who developed ANLL as a second malignancy did poorly. The median survival of 2 months in this group was similar to reports of ANLL in patients receiving alkylating agents for ovarian cancer or combined modality therapy for Hodgkin's disease[20] [21] Only one of our patients obtained a complete remission which is similar to the 10% response rate reported in the literature.[9]

Treatment in adults with ALL is the most rewarding aspect of adult acute leukemia. Gee et al.[3] reported a 78% remission rate in adults with ALL with the "L2" protocol at the Memorial Sloan-Kettering Cancer Center. Median survival was 33 months. Our patients treated with similar protocols had a complete remission rate of 83% a median survival of 33.5 months. Other series have reported complete remission rates of 43-93% with the best results using vincristine, prednisone and daunorubicin.[2] Arlin et al. have recently reported preliminary results with the "L10" protocol showing an 89% complete remission rate.[1] They found that no patient remaining in complete remission beyond the consolidation phase (usually the first 4 months) has yet relapsed.

We are particularly pleased to see the increasing numbers of long survivors in both ALL and ANLL. In the adult ALL group the percentage is approaching 40-50% and the ANLL is approaching 15-20%.

Finally, some comment should be made regarding the patient morbidity and cost of these aggressive and complicated chemotherapeutic protocols. It has been estimated[9] that the cost of intensive chemotherapy in the first year is approximately $48,000, comparing with the costs of hemodialysis, renal transplantation. Typical patients who present with ANLL may require a 4-6 week initial hospitalization for remission induction. The consolidation protocols involve short 5-7 day hospitalization for infusion therapy and the patients are able to be discharged in the intervals. It is our hope to use subcutaneous infusion pumps to avoid some of these hospitalizations. There is certainly a significant morbidity related to the aggressive chemotherapy in terms of infection at the nadir of chemotherapeutic WBC suppression, and hospitalizations for septicemia and bleeding. However, once the routine has been established the patients are able to lead functional lives and many have been able to work when maintenance chemotherapy is begun. In the community setting there is great flexibility as to physician availability and office chemotherapy, which we believe add to patient compliance with the protocols.

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# Endoscopic Papillotomy: A New Method for the Treatment of Common Duct Stones

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**ABSTRACT—Endoscopic papillotomy is a new procedure for the treatment of common duct stones and other lesions of the Ampulla of Vater. Since September, 1978, the procedure has been attempted twenty-seven times in Connecticut. Twenty-two (81 percent) of the patients had common duct stones, two had ampullary carcinoma, and three, ampullary stenosis. A successful papillotomy incision was achieved in nineteen patients (70 percent).**

**Stones were completely removed or demonstrated to have passed spontaneously in twelve of the fifteen patients with common duct stones who underwent successful papillotomy. Complications occurred in four patients (15 percent). Three of those patients required surgery. One patient expired 10 days after emergency surgery for massive hemorrhage.**

**Endoscopic papillotomy is a viable alternative to common duct exploration, particularly in the older, poor-risk surgical patient. The expected morbidity and mortality rates in large published series are 7 percent and 1.4 percent respectively.**

Endoscopic papillotomy (EP) is a new method for the treatment of common duct stones and certain lesions of the Ampulla of Vater. Since the development of the procedure in Germany in 1974, approximately 6,000 endoscopic papillotomies have been carried out world-wide[7]. Ten percent of these have been done in nine endoscopic units in the United States[8]. This procedure is a therapeutic extension of endoscopic retrograde cholangiopancreatography (ERCP) which is one of the most effective methods for the diagnosis of disorders of the pancreas and biliary tract. In experienced hands, endoscopic papillotomy has proven to be a safe and effective method of treating common duct calculi, particularly in patients who are poor operative risks. The method is also suitable for treatment of selected cases of ampullary carcinoma and ampullary stenosis.

## Material and Methods

Since September, 1978, twenty-seven patients have been subjected to endoscopic papillotomy in Connecticut. Twenty-two of these were done at Hartford Hospital, two at the Newington Veterans Administration Hospital, and one each at Yale-New Haven Hospital, Hospital of St. Raphael, and New Britian General Hospital. Pertinent clinical data is presented in Table I.

The method is initially identical to that used for endoscopic retrograde cholangiopancreatography. After pre-medication with hydroxyzine, 100mg. and atropine, 0.5 mg. intramuscularly, the patient is positioned on the fluoroscopy table. Sedation is achieved with intravenous meperidine, 50-100 mg. and diaze-

Table I
CLINICAL DATA AND RESULTS OF ENDOSCOPIC PAPILLOTOMY

| | *Number* | *%* |
|---|---|---|
| Total Patients | 27 | 100 |
| Male | 17 | 63 |
| Female | 10 | 37 |
| Age Range 44-93 years | | |
| Mean 73.2 years | | |
| Diagnoses | | |
| Common Duct Stones | 22 | 81.5 |
| Previous Cholecystectomy | 13 | |
| Gallbladder Intact | 9 | |
| Ampullary Carcinoma | 2 | 7.4 |
| Ampullary Stenosis | 3 | 11.1 |
| Successful Papillotomy | 19 | 70 |
| Common Duct Stones | 15/22 | 68 |
| Stones Removed | 8 | |
| Stones Passed | 4 | |
| Stones Retained | 3 | |
| Ampullary Carcinoma | 2/2 | 100 |
| Ampullary Stenosis | 2/3 | 66 |
| Failure of Papillotomy | 8 | 30 |
| Complications | 4 | 15 |
| Hemorrhage | 2 | |
| Stone Impaction | 1 | |
| Cholecystitis | 1 | |
| Fatality | 1 | 3.7 |

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pam, 10-20 mg. Duodenal paralysis is accomplished with an additional intravenous dose of atropine, 0.5 mg. and occasionally glucagon, 0.25-1.0 mg. The common bile duct is then cannulated and visualized with 60% diatrizoate. The diagnosis of common duct stones, ampullary carcinoma, or distal bile duct stricture or stenosis is then confirmed by spot films and overhead radiographs.

If a treatable lesion is found, the diagnostic cannula is withdrawn and a modified cannula containing an electrified wire is positioned within the distal segment of the common bile duct under fluoroscopic control. A blended cutting and coagulation current is then passed through the wire from a suitable electrosurgical generator. The papilla is incised for a variable distance along the common bile duct, depending on the nature of the lesion and the size of the retained stones.

When a suitable opening has been made in the distal common bile duct, stones will either pass spontaneously (Figure 1), or can be extracted with a collapsible stone basket passed through the duodenoscope (Figure 2).

## Results

The results of attempted endoscopic papillotomy in our initial twenty-seven patients are shown in Table I. A successful papillotomy incision was accomplished in nineteen patients (70 percent). Fifteen of those patients had common duct stones; in eight, the stones were removed by basket at the time of papillotomy and in four, the stones were shown to have passed spontaneously by subsequent ERCP. Three of the patients had stones left behind, two of whom have remained asymptomatic and have not had follow-up studies. One patient had two of his three stones removed, but the third impacted in the Ampulla of Vater five days later and had to be removed surgically. Two elderly patients with ampullary carcinoma were successfully palliated by incision of the tumor endoscopically, relieving obstruction to both the common bile and pancreatic ducts. Two patients with jaundice and cholangitis due to short strictures of the common bile duct were treated successfully with EP.

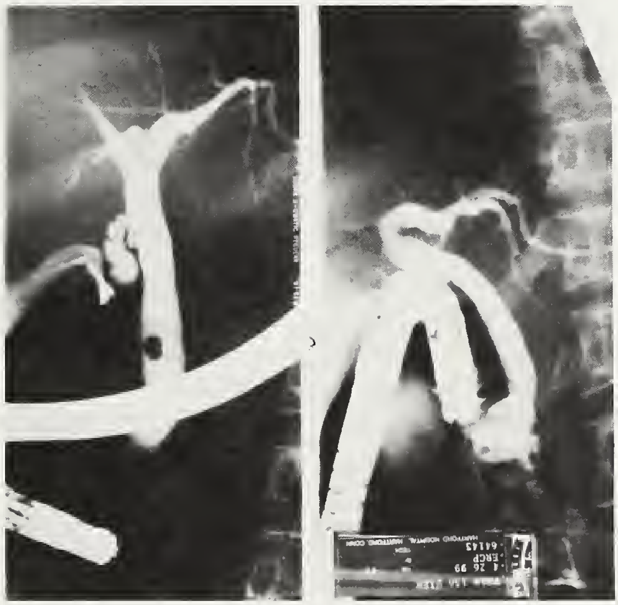

Figure 1

Endoscopic cholangiograms in a 48-year-old woman with cholangitis. A solitary 0.5 cm. stone is shown on the left. Five weeks after papillotomy, a repeat study (right) shows that the stone has passed spontaneously, and there is rapid run-off of contrast into the duodenum

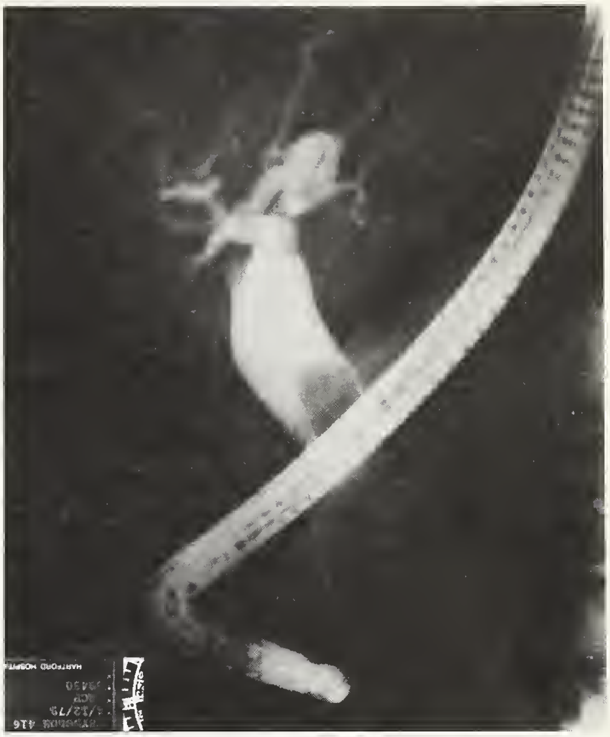

Figure 2

Endoscopic cholangiogram in a 78-year-old man with obstructive jaundice, showing a 1.6 cm. stone in a dilated common bile duct. This stone was subsequently removed by basket extraction after endoscopic papillotomy

An adequate papillotomy incision could not be achieved in eight patients (30 percent), seven with common duct stones and one with ampullary stenosis. All of these patients subsequently had successful surgical treatment.

There were four complications in this initial series. Two patients had hemorrhage, one occurring four days after the procedure and stopping spontaneously after four units of blood. The other hemorrhage was massive, occurred during the procedure and required immediate emergency surgery. This patient, a 70-year-old man, and the only fatality in the series, expired of cardiovascular complications ten days postoperatively. A third patient suffered impaction of a retained stone as noted above. The fourth complication was that of acute, gangrenous cholecystitis occurring five days after papillotomy and removal of common duct stones. This patient was treated successfully by cholecystectomy.

## Comments

Common duct exploration, the conventional treatment for common duct stones, carries a significant morbidity and mortality, particularly in the older patient with associated diseases. Endoscopic papillotomy appears to offer a viable alternative mode of therapy, particularly in the poor surgical risk patient. Our experience with the procedure is relatively modest, encompassing twenty-seven patients over nine months. The success rate can be expected to increase, and the morbidity and mortality to decline with increasing experience of the operator. Safrany[3], reporting on a series of over 3800 patients collected from fifteen world-wide endoscopy units, reports an overall 93 percent success rate. Complications in this series occurred in seven percent of the patients, and the mortality rate was 1.4 percent.

In our experience, a most impressive feature of this treatment is the tolerance of the patient to a successful papillotomy. The patient's response to the procedure is comparable to that of a routine diagnostic ERCP. The patient is usually able to take a regular diet by suppertime of the day of the procedure and may be out of bed by that time. Discharge can be anticipated two or three days afterwards. However, since complications, such as stone impaction and bleeding, can occur up to a week after the procedure, the patient should be warned to report all relevant symptoms to his physician immediately.

Endoscopic papillotomy is a technically difficult procedure to learn. It requires extensive experience in ERCP and expert knowledge of the anatomy of the Papilla of Vater and the distal common bile duct. Expert radiologic support and high-resolution fluoroscopic equipment must be available, particularly for the placement of the papillotome within the ampullary segment of the bile duct.

Endoscopic retrograde cholangiopancreatography represents a dramatic step forward in the diagnosis of pancreatic and biliary tract diseases. Endoscopic papillotomy has extended this technique into the realm of therapeutics.

## ACKNOWLEDGMENTS

The authors wish to express their appreciation to Dr. Laszlo Safrany of Wilhelmshaven, West Germany, for teaching us how to perform endoscopic papillotomy, and to Mark English and Dr. William Macaulay of Hartford Hospital for engineering and surgical support respectively.

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# Ischemic Colitis: Current Trends

PAUL A. BARCEWICZ, M.D. AND JOHN P. WELCH, M.D.

**ABSTRACT—Our experience with twenty-four patients with ischemic colitis is presented with discussion of the present understanding of the disease. The data point to a marked preponderance in females (79%) and demonstrate a high incidence in patients less than fifty years of age (47%). Ischemic colitis should be considered in all patients with bloody diarrhea.**

Ischemic colitis is a recently defined clinical entity often overlooked in the differential diagnosis of lower gastrointestinal bleeding. While the differential diagnosis of bloody diarrhea, particularly in the older patient, traditionally includes diverticulosis, carcinoma, and granulomatous, ulcerative, or infectious colitis, ischemic colitis is often forgotten. Similarly, in the discussion of the various forms of mesenteric vascular ischemia, ischemic colitis is usually overshadowed by more dramatic and lethal entities such as mesenteric arterial embolism and thrombosis, mesenteric venous thrombosis, and so-called "nonocclusive mesenteric vascular disease." Curiously, the latter may represent one end of the spectrum of ischemic colitis. This review was undertaken in an attempt to clarify the incidence, presentation and clinical course of ischemic colitis.

## Materials and Methods

A retrospective chart review of all patients treated at the Hartford Hospital between 1970 and 1977 for all types of ischemic bowel disease was undertaken. The diagnosis of ischemic colitis was made on the basis of the history, physical and laboratory findings, and radiographic studies, according to the criteria established in the literature.[1] Most patients had transient clinical findings (classified as "mild" disease), while others had developed peritonitis and gangrene of the bowel.

## Demography

Twenty-four patients were identified in whom the diagnosis of ischemic colitis was certain (Table 1). There were ten patients (42%) age fifty or younger. There were nineteen females (79%) and five males (21%).

Table I

DEMOGRAPHY OF ISCHEMIC COLITIS
24 PATIENTS, HARTFORD HOSPITAL

| *Age:* | *Male* | *Female* | *"Mild" Disease** | *Gangrenous*** |
|---|---|---|---|---|
| 10-20 | | 1 | 1 | |
| 21-30 | | 2 | 1 | 1 |
| 31-40 | 1 | 1 | 2 | |
| 41-50 | | 5 | 3 | 2 |
| 51-60 | 1 | 6 | 7 | |
| 61-70 | 1 | 3 | 3 | 1 |
| 71-80 | 2 | 1 | 1 | 2 |
| Totals: | 5 (21%) | 19 (79%) | 18 (75%) | 6 (25%) |

*See text for definition.
**Verified by laparotomy.

## Associated Factors

Four of the ten patients age fifty or less were taking estrogens either as oral contraceptives or as postmenopausal replacement at the time of admission to the hospital. Three others had taken oral contraceptives in previous years.

## History

All patients complained of bloody diarrhea ranging from hours to four days in duration, sometimes associated with nausea and vomiting. All complained

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of crampy lower abdominal pain, but the bloody diarrhea dominated the clinical picture.

### Clinical and Laboratory Findings

All patients had low grade fever and leukocytosis, averaging 13,700 white blood cells per $mm^3$ in mild forms of the disease and 20,000 per $mm^3$ with gangrene of the colon. Hypoactive bowel sounds, moderate abdominal distention, lower abdominal tenderness, (usually without evidence of peritonitis), and hemoccult positive stools were characteristic. Sigmoidoscopy revealed normal mucosa and blood issuing from above.

Barium enemas performed in all cases demonstrated thumbprinting or less often diffuse spasm (Figure 1). One aortogram with selective mesenteric injections revealed normal patent vasculature (Figure 2). The anatomic sites of disease revealed by contrast studies are summarized in Table 2.

### Course of Disease

Eighteen patients (75%) had spontaneous resolution of the disease in one to five days ("mild disease"). One of these went on to documented stricture formation. Follow-up barium enemas were not performed in the absence of symptoms (Figure 3). One patient was readmitted one year subsequently with a second episode of ischemic colitis. Six patients (25%) developed gangrene of the colon and required resection. All patients with gangrenous bowel had involvement of the descending and/or sigmoid colon. No patients died of their disease.

### Discussion

Ischemic colitis is a relatively mild form of mesenteric vascular disease, which in its severe form is confused with non-occlusive mesenteric vascular disease. First described by Boley et al in 1963,[2] ischemic colitis should be considered in all patients with lower gastrointestinal bleeding. Its pathophysiology and clinical course have been thoroughly described in other reports.[1 3 4 5 6] In early reports most patients were elderly,[4] but there is now documentation of the disease among young patients.[7 8 9 10 11 12] Our results corroborate this point, although we have not demonstrated a predilection for right-sided lesions in young patients described by Clark and colleagues.[7]

We have confirmed that bloody diarrhea dominates the clinical picture in most patients. Moderate to mild abdominal pain is usually present, sometimes accompanied by nausea and vomiting. Patients appear only moderately ill, and fever and leukocytosis are low grade. The abdomen is soft, quiet, moderately

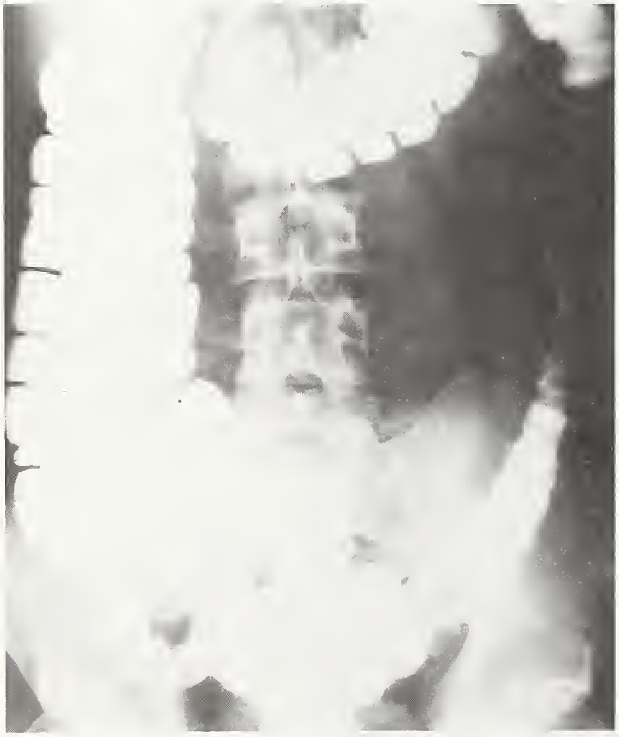

Figure 1

Barium enema performed soon after hospital admission demonstrating "thumbprinting" in the descending colon caused by submucosal edema.

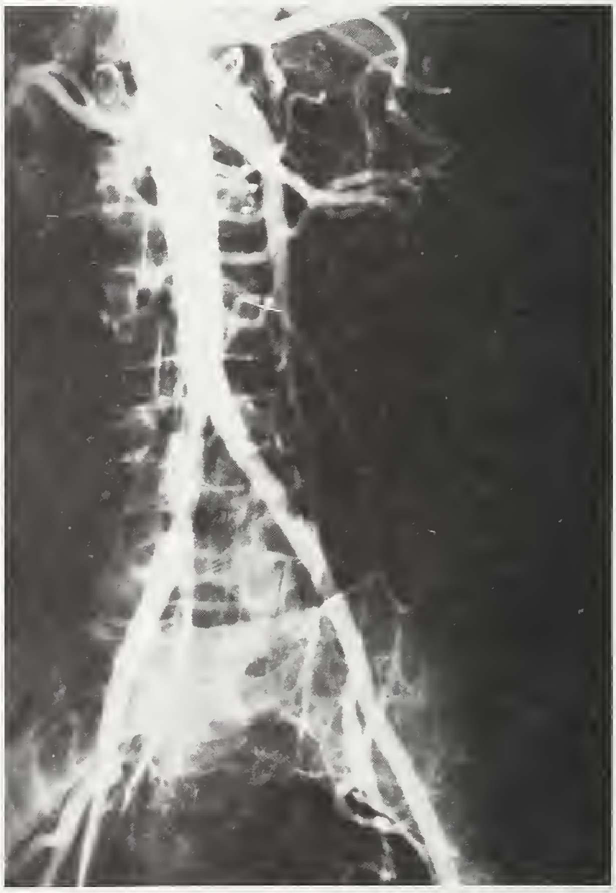

Figure 2

Selective mesenteric arteriogram in patient with classic barium enema findings of ischemic colitis. Note patency of major vasculature.

Table 2

DISTRIBUTION OF ISCHEMIC COLITIS

| *Anatomic Site Affected* | *Number* |
|---|---|
| Ascending Colon | 2 |
| Transverse Colon | 8 |
| Descending Colon | 11 |
| Sigmoid Colon | 3 |

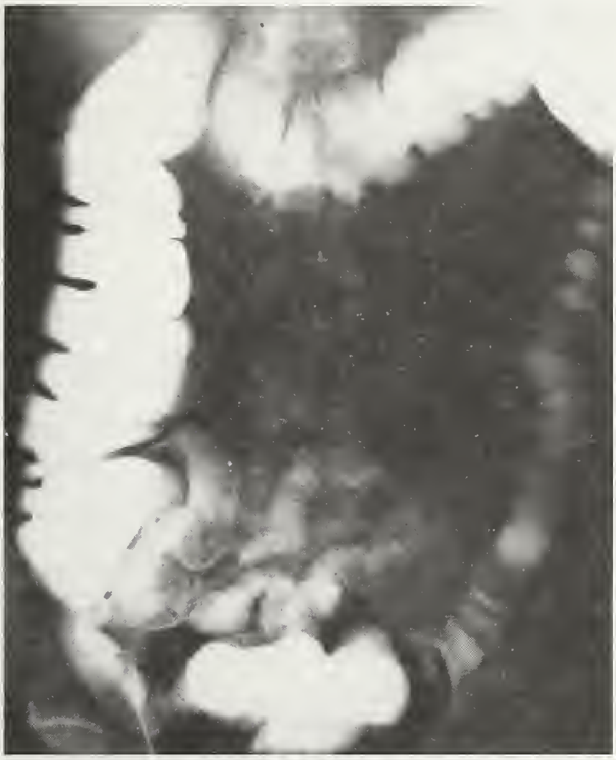

Figure 3
Follow-up barium enema shows resolution of previous thumbprinting (same patient as in Figure 1).

distended and diffusely tender in the lower quadrants. The excruciating abdominal pain out of proportion to physical findings (as seen in mesenteric vascular infarction) is not characteristic. If signs of peritonitis are present, progression to the gangrenous form of the disease may have taken place.

Marston et al[3] originally described three forms of ischemic colitis: transient with healing, fibrosis with stricture, and gangrene. While this classification has been preserved in current textbooks, Marston[1] has revised the classification to include two categories: mild disease and gangrene. The latter subdivision fits better with acute clinical management, since the mild form of ischemic colitis spontaneously improves with supportive measures (bowel rest, intravenous fluids and possibly antibiotics), while the latter demands emergency operation. Patients with a worsening clinical picture or with peritonitis should undergo operation. Gangrenous segments of bowel are resected with reanastomosis or temporary diversion to be followed later by reanastomosis.

Sigmoidoscopy is important in ruling out other forms of colitis. Blood is seen coming from above and the mucosa is usually normal. Ischemic changes have been documented with sigmoidoscopy,[13] but usually the disease lies in the range of the colonoscope only.[14]

The barium enema is the most useful early diagnostic maneuver. The diagnosis is confirmed with the demonstration of thumbprinting (a nonspecific sign of submucosal edema). Barium enema findings can change rapidly; thumbprinting may disappear in forty-eight hours or persist for weeks.[1] Intramural barium and mucosal ulceration may be seen as well.[15] Angiography is usually unnecessary[16] and demonstrates patent vessels (Figure 2).

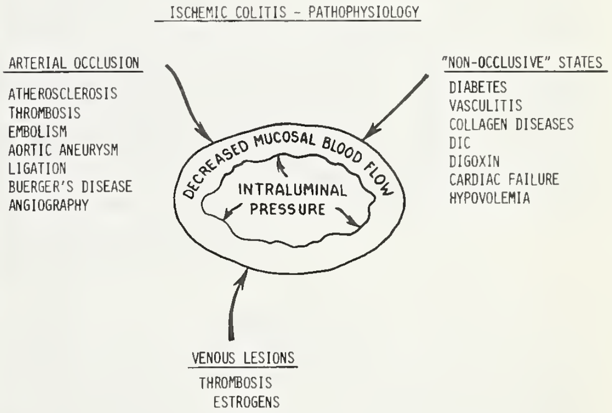
ISCHEMIC COLITIS – PATHOPHYSIOLOGY
ARTERIAL OCCLUSION
ATHEROSCLEROSIS
THROMBOSIS
EMBOLISM
AORTIC ANEURYSM
LIGATION
BUERGER'S DISEASE
ANGIOGRAPHY
"NON-OCCLUSIVE" STATES
DIABETES
VASCULITIS
COLLAGEN DISEASES
DIC
DIGOXIN
CARDIAC FAILURE
HYPOVOLEMIA
DECREASED MUCOSAL BLOOD FLOW
INTRALUMINAL PRESSURE
VENOUS LESIONS
THROMBOSIS
ESTROGENS

Figure 4
Etiology and pathophysiology of ischemic colitis.

The course of ischemic colitis is typically one of spontaneous improvement. Fibrosis with stricture may develop at a later time, in up to one-third of cases, but surgical intervention is usually not needed unless there are unremitting symptoms of obstruction or neoplasm is suspected.[1]

### Acute Management

Since gangrene may ensue in any patient, careful observation, "resting" of the gastrointestinal tract, and administration of intravenous fluid and antibiotics (because of the loss of the mucosal barrier) are indicated. There is no place for steroids except in the rare instance when vasculitis is suspect.

If operation is necessary, all involved areas of colon should be resected. In mild cases, necrosis is limited to the mucosa, with healthy underlying musculature and patent major vessels. The bowel may appear normal exteriorly and should be opened and carefully examined in the operating room. Whether resection is essential in such cases is unknown since the natural course of patients with mucosal infarction alone is not known. Passage of a long mucosal cast per rectum, followed by patient recovery and the development of a colonic stricture has been observed by one of the authors. If anastomosis is elected, the united ends must not be ischemic since leakage or later stricture may result. Temporary diversion, followed by later reanastomosis is preferred if there is contamination or questionable viability of the retained bowel.

### Pathophysiology

The pathophysiology of ischemic colitis is obscure. Similar radiographic and pathologic findings have been reproduced in the laboratory.[19] It is a recognized complication of abdominal aortic aneurysmectomy when a patent inferior mesenteric artery is sacrificed, but such cases have been excluded from this series. Ischemic colitis has been associated with multiple conditions that interfere with small vessel perfusion of the colon but the cause is still unknown (Figure 4). Four of our ten patients age 50 or less were taking oral estrogens, either as contraceptives or postmenopausal replacement. The association between estrogens and thrombotic states is well-proven[17] but the possible connection with ischemic colitis is purely conjectural.[8 9 11 12 18]

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# The Comparative Utility of Serum Creatine Kinase Versus Serum Aldolase in the Evaluation of Muscle Disorders

DAVID GIESKER, M.D. AND GEORGE N. BOWERS, JR., M.D.

**ABSTRACT—The comparative utility of serum creatine kinase versus aldolase activity measurements in the diagnosis and management of skeletal muscle disease is reviewed. Creatine kinase is the more sensitive and specific of the two enzymes. Aldolase adds little information; its continued clinical use results from its historical position as the first muscle enzyme studied in these conditions. The specificity of serum aldolase is reduced by its elevation in many other diseases (e.g., hematologic and hepatic disorders) and its spurious elevation due to specimen hemolysis. Serum enzymes should be determined only on well-rested patients who have undergone no recent iatrogenic manipulations.**

## Introduction

Clinical researchers in muscle disorders have studied the activities of over 40 enzymes in serum and up to 60 in muscle.[1] Two of the most extensively studied enzymes are aldolase*[2] and creatine kinase**[3]. During the past few years there has been a sharp increase in the number of requests to this hospital's clinical chemistry laboratory for the assay of serum aldolase activity as part of the initial workup of patients with suspected muscle disease. We were surprised by these requests since current texts on clinical enzymology[4-6] and medicine[7] [8] clearly cite the advantages of measuring creatine kinase instead of aldolase, with the only possible exception being in polymyositis. We initiated an intensive search of the literature to see if new data had recently appeared which might have changed the relative clinical utility of these two enzyme measurements. Our review showed a dearth of recent publications on serum enzymes in myopathies, particularly in respect to aldolase. We were thus forced to return to earlier literature, much of it now decades old, in order to obtain sufficient patient comparisons between aldolase and creatine kinase.

From the methodological viewpoint, analytical measurements prior to the 1970's tended to give an advantage to aldolase in comparison with creatine kinase since the former assay has changed very little if at all.[9] In contrast, today's assays of creatine kinase, employing sulfhydryl compounds and several other recent modifications, more fully activate the enzyme and reduce the effects of various inhibitors and side reactions.[10] [11] [12] Therefore, cautious interpretation of earlier clinical studies in which these thiol reactivators were not employed is advised.[13]

In this review, we have paid special attention to Duchenne's muscular dystrophy and polymyositis, two of the most common and debilitating muscle disorders, in order to re-evaluate for ourselves the comparative utility of aldolase versus creatine kinase in the diagnosis and management of these disorders.

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**Aldolase*, EC 4.1.2.13, the recommended name is fructose-biphosphate aldolase.

***Creatine kinase*, EC 2.7.3.2, the recommended name is creatine kinase.

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### Activity in Human Tissues

Aldolase is one of the primary enzymes of glycolysis, catalyzing the reaction:

$$\underline{\text{D}}\text{-fructose-1,6-diphosphate} \xrightleftharpoons{\text{Aldolase}} \text{dihydroxyacetonephosphate} + \underline{\text{D}}\text{-glyceraldehyde-3-phosphate}$$

Since glycolysis is vital to cellular metabolism, it is not surprising that the enzyme is widely distributed in mammalian tissues. Like other glycolytic enzymes, aldolase is not bound tightly to cellular membranes or mitochondria but is found "free" within the cytoplasm. Theoretically, such free enzymes may easily leak into the circulation as a result of either inductive stimuli or cellular damage, even in the absence of frank tissue necrosis.[14] Table 1 lists the aldolase activity found in various tissues in comparison to the reference values for the serum activity of healthy individuals.[6, 15-17] It is obvious from Table 1 that hemolysis occurring during specimen collection, transport or separation from the clot will actifactually increase aldolase activity. The high activity in the liver also represents a potential source of enzyme which can reduce the clinical specificity for muscle disorders.

Table 1

ACTIVITY* OF ALDOLASE AND CREATINE KINASE IN HUMAN TISSUES

| *Tissue* | *Aldolase* | *Creatine Kinase* |
|---|---|---|
| Skeletal muscle | 60 | 2000 |
| Cardiac muscle | 6 | 500 |
| Cerebral cortex | 7 | 500 |
| Kidney | 2 | 5 |
| Lung | 0.5 | 0.01 |
| Liver | 7 | 0 |
| Erythrocyte | 1 | 0 |
| Serum | 0.003 (3 U/L) | 0.05 (50 U/L) |

*All activities converted to International Units (U = $\mu$mol/min) per gm wet tissue at 30°C (U/g). Aldolase data originally in Buccher units (= 1.09 $\mu$mol x g$^{-1}$ x h$^{-1}$ at 25°C) in Ref. 15 was converted to $\mu$mol x min$^{-1}$ x g$^{-1}$ at 30°C assuming a temperature factor of 1.5.

Creatine kinase data combined from Ref. 6, 16 and 17 with calculations to U/g at 30°C when required.

In contrast to the ubiquitous distribution characteristic of aldolase, creatine kinase is primarily an enzyme of muscle. Creatine kinase catalyzes the reaction:

$$\text{Creatine} + \text{adenosine triphosphate (ATP)} \xrightleftharpoons{\text{creatine kinase}} \text{creatine phosphate} + \text{adenosine diphosphate (ADP)}$$

Here high energy phosphate is transferred between ADP and creatine. Creatine phosphate is the major high energy storage compound in muscle, and is thus critical for muscular function. As shown in Table 1, the activity of creatine kinase found in skeletal muscle is orders of magnitude higher (2000 U/g vs 60 U/g) than that of aldolase. Although many factors contribute to the activity and turnover rate of an enzyme in serum,[18] experience has shown that high enzyme activity in muscle is regularly mirrored in the serum of patients with a myopathy. The fact that most other tissues (including erythrocytes and liver) have little or no creatine kinase makes serum elevation of creatine kinase potentially more specific for muscle injury than are aldolase elevations.

### Serum Activity in Association with Myopathies

In 1949 Sibley and Lehninger[19] published their pioneer study correlating serum aldolase activity with muscle disease. Their most striking finding was a marked elevation in two patients with muscular dystrophy. Their findings were soon confirmed and extended by Schapira et al.[20] Thus, a correlation between elevated serum aldolase activity and muscle disease was chronologically well established prior to the study of the numerous other muscle enzymes.[1] These enzymes include the following: acid phosphatase, aconitase, alkaline phosphatase, aspartate, aminotransferase, ATPase, cholinesterases, creatine kinase, cytochrome oxidase, enolase, fumerase, glucose-6-phosphate dehydrogenase, glutathione reductase, hexokinase, isocitrate dehydrogenase, lactate dehydrogenase, lysozyme, malate dehydrogenase, myokinase, 5′-nucleotidase, phospharylases, pyruvate kinase, succinate dehydrogenase and triosephosphate isomerase as well as many others.

A full decade later in 1959 Ebashi et al[21] demonstrated that creatine kinase activity in serum was elevated in 84% of their patients with Duchenne's muscular dystrophy. These authors suggested the future use of this enzyme in the diagnosis of Duchenne's muscular dystrophy. During the 1960's numerous articles examined creatine kinase in a variety of myopathies. The general conclusion of these publications[13, 22-34] was that creatine kinase is clearly the enzyme of choice over aldolase and the other commonly available enzymes. As shown in Table 2 both the percentage of patients with elevations and the magnitude of these elevations were greater for creatine kinase than for aldolase in all of these diseases. Thus creatine kinase is indeed more sensitive—that is, a) elevated in more patients with the disease, and b) elevated to a greater degree above the reference limit (xURL). Moreover, the female carrier state of Duchenne's muscular dystrophy is more readily detected by creatine kinase. For example, Hughes[35] noted that 86% of his known carriers had creatine kinase elevations averaging 3.5

Table 2

ALDOLASE AND CREATINE KINASE ACTIVITY IN SERUM OF PATIENTS WITH MYOPATHIES

| *Myopathy* | *Aldolase* | | *Creatine Kinase* | |
|---|---|---|---|---|
| | %(n) | xURL(n) | %(n) | xURL(n) |
| *Muscular Dystrophies* | | | | |
| Duchenne's | 84(334) | 11(266) | 96(264) | 65(196) |
| Limb-Girdle | 12(16) | 2(16) | 72(51) | 16(51) |
| Facioscapulohumeral | 33(15) | 2(15) | 76(17) | 6(17) |
| Myotonic | 19(16) | 2(16) | 20(20) | 5(20) |
| *Inflammatory Myopathy* | | | | |
| Polymyositis/<br>Dermatomyositis | 65(88) | 3(33) | 70(71) | 10(69) |

%(n) = the percentage of all patients with the disease (n) having values above the upper reference limit, compiled from References 13, 22-34.

xURL(n) = times the upper reference (normal) limit established in healthy individuals in all patients (n) with the disease.

xURL versus only 33% elevations of aldolase averaging only 1.3 xURL. Genetic counseling today in Duchenne's muscular dystrophy is thus heavily dependent upon creatine kinase determinations. (It should be noted that this discussion has concerned only the common, lethal, sex-linked form of Duchenne's muscular dystrophy and not the less common "benign" and autosomally-transmitted forms.)

In the other dystrophies (Table 2) the percentage of patients with serum enzyme elevations and the magnitude of these elevations are less striking than those associated with Duchenne's muscular dystrophy. It is, however, clear that the sensitivity of creatine kinase exceeds that of aldolase in every instance.

Creatine kinase also maintains its superiority in the diagnosis and treatment of polymyositis, as shown in Table 2. Serum enzymes in general have proved useful in monitoring various stages of this disease.[27 32 36] The increased enzyme activities frequently present in both acute and chronic polymyositis can aid in diagnosis and signal the need for steroid therapy.[36] Enzymes may furthermore be a harbinger of successful therapy—their activities decrease 3 to 4 weeks before clinical improvement of muscle function[37] and usually return to normal in an average of 14 weeks.[36] (Enzymes are of less value in predicting relapse in a patient on steroid therapy: creatinuria is a more sensitive indicator of relapse.)[36] In patients with the chronic stage of disease, and in those both receiving and not receiving steroid therapy, there are occasional reports of mildly elevated aldolase activity (to 2.5 xURL)[27 36] with simultaneous "normal" creatine kinase activity. Such findings have prompted some authors to recommend obtaining aldolase in addition to creatine kinase in polymyositis patients.[36 38] However, aldolase elevations to 2.5 xURL occur in association with many other disorders (Tables 3 and 4) and with hemolyzed specimens. This lack of specificity could easily cause the occasional mild aldolase activity elevation in the face of a "normal" creatine kinase activity.

Table 3 lists several other disorders involving skeletal muscle. From this table it is apparent that aldolase offers no advantage over creatine kinase in the primary skeletal muscle disorders. Note also that the time-honored finding[29] of normal enzyme activities in muscle disease of neurogenic origin is clearly reflected in Table 3.

Table 4 lists disorders in which either one or both of the enzymes under consideration may be elevated. These conditions should be searched for and, if present, their influence carefully weighed before serum enzyme elevations are attributed to skeletal muscle disease. Table 4 also emphasizes the nonspecificity of aldolase (particularly at low activity elevations) versus creatine kinase in the presence of hepatic and hematologic diseases. When central nervous system or myocardial disorders can be excluded, the likelihood of an elevated serum creatine kinase activity representing skeletal muscle disease is high.

To avoid misleading factitious enzyme elevations it is essential that any patient being examined for skeletal muscle disease be well rested (avoid strenuous exercise) and be free of recent iatrogenic manipulations such as surgery and intramuscular injections when the samples are drawn.

## Conclusions†

1. A review of the literature shows that creatine kinase activity in serum is a clinically sensitive and specific measurement for the evaluation of patients

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†After compiling our data, we became aware of the chapter on muscle disease by S.B. Rosalki in Wilkinson's textbook (reference number 5). He took an approach similar to ours and reached many of the same conclusions. His review is more extensive and includes information on other enzymes such as lactic dehydrogenase (LD) and aspartate aminotransferase (ASAT). This chapter is highly recommended for the reader in search of more detail and further references on the subject of serum enzymes in muscle disease.

Table 3

ALDOLASE AND CREATINE KINASE IN MISCELLANEOUS SKELETAL MUSCLE DISORDERS

References in Parenthesis ( ).

| *Primary Skeletal Muscle Diseases* | *Aldolase* | *Creatine Kinase* |
|---|---|---|
| Alcoholic myopathy | — | 2-5 xURL (40) |
| Familial pinodic paralysis | — | with attacks (41) |
| Gangrene | usually ↑ (39) | usually ↑ (42) |
| Trichinosis | usually ↑ (39) | — |
| Rhabdomyolysis | — | 200 xURL (43) |
| Myopathy with myoglobinuria | — | elevated (44) |
| *Neurogenic Muscle Diseases* | | |
| Amyotrophic lateral sclerosis | — | WRL (21) |
| Myosthenia gravis | 7% mild ↑ (29) | WRL (5) |
| Poliomyelitis | 4% mild ↑ (29) | WRL (21, 24) |
| Other neurogenic muscular diseases with muscular atrophy | 1% mild ↑ (29) | 8% mild ↑ (21) |

(xURL) = times upper reference (normal) limit established in healthy individuals.
(WRL) = within reference (normal) limit established in healthy individuals.

Table 4

ALDOLASE AND CREATINE KINASE IN VARIOUS DISORDERS

References in Parenthesis ( ).

| *Myocardial Disease* | *Aldolase* | *Creatine Kinase* |
|---|---|---|
| Myocardial Infarct | 5-8 xURL (39) | 7-12 xURL (6) |
| *Hepatic Disorders* | | |
| Viral hepatitis | 7-20 xURL (39) | WRL (26, 47) |
| Cirrhosis | 1-2 xURL (45) | WRL (47) |
| Obstructive liver disease | 1-2 xURL (45) | WRL (26) |
| Metastatic cancer to liver | 2 xURL (46) | WRL (47) |
| *Hematologic Disorders* | | |
| Megaloblastic anemia | 10-13 xURL (39) | WRL (26) |
| Hemolytic anemia | 2-6 xURL (45) | WRL (48) |
| Granulocytic leukemia | 6 xURL (39) | WRL (26) |
| *CNS Disorders* | | |
| Acute schizophrenia | 1-6 xURL (49) | 2-10 xURL (49) |
| Acute psychosis (not schizophrenia) | 1-13 xURL (49) | 3-12 xURL (49) |
| Cerebral vascular accident | — | 1-10 xURL (50) |
| Delirium tremens | 2-3 xURL (45) | 1-15 xURL (40) |
| Epileptic convulsions | WRL (65) | 1-10 xURL (51) |
| *Other Disorders* | | |
| Acute pancreatitis | 1-3 xURL (45) | WRL (52) |
| *Iatrogenic Manipulation* | | |
| Post-surgery | WRL (45) | 3-10 xURL (54) |
| Intramuscular injections | occ. ↑ (53) | 2-4 xURL (48) |
| *Other Conditions* | | |
| Moderate exercise | 1-3 xURL (55) | 1-5 xURL (56) |
| Endocrine myopathy (myxedema) | 1-2 xURL (45) | 1-5 xURL (57) |
| Malignant hyperthemia | — | ↑ (44) |

with skeletal muscle disorders. It is superior to all other serum biochemical tests in the diagnosis and the detection of the sex-linked carrier state of Duchenne's muscular dystrophy. In comparison to simultaneously determined aldolase, creatine kinase is clearly more sensitive and specific in detecting the inflammatory and dystrophic disorders discussed.

2. Creatine kinase elevation can be equated to skeletal muscle injury if one excludes elevations caused by improper patient preparation (recent exercise), iatrogenic manipulation (IM injections) and a limited number of diseases (e.g., CNS and myocardial).
3. Aldolase determinations add little clinical information; their continued use reflects predominantly the historical position of aldolase as the first enzyme studied in muscle disease.
4. If aldolase determinations are to be made, the interpretation of elevations in the range of 2-3 xURL must be cautious since many other diseases (e.g., hepatic, hematologic, neurologic) are associated with similar elevations and hemolysis causes spurious elevations.

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# Chronic Pancreatitis: The Direct Surgical Approach

DANIEL J. SCOPPETTA, M.D., WILLIAM P. MACAULAY, M.D.,
ROBERT S. ROSSON, M.D. AND A. DAVID DREZNER, M.D.

**ABSTRACT—The results of 29 pancreatic operations for therapy in chronic pancreatitis were reviewed. A treatment plan based on preoperatively defined anatomy, modified by intra-operative findings, is presented. Using this approach, the proper role of surgery is more completely defined.**

The role of surgery in the management of chronic relapsing pancreatitis continues to be defined. Operative intervention depends on the site and severity of disease within the gland and the biliary and pancreatic ductal systems. Endoscopic retrograde cholangiopancreatography permits preoperative delineation of ductal pathology. Combined with intraoperative pancreatic ductography and gross glandular appearance an individualized procedure can be selected which not only relieves ductal obstruction but also preserves as much functioning pancreas as possible. We reviewed the Hartford Hospital experience over the past eight years in order to demonstrate our approach to the surgical management of chronic pancreatitis.

### Patient Selection

All patients were operated upon for relief of intractable pain. Other associated indications were symptomatic pleural effusions, steatorrhea, and pancreatic ascites. Pancreatitis was documented using a combination of history, signs, symptoms, x-ray data and laboratory findings. All were confirmed at laparotomy.

All patients had symptoms for at least one year, most for more than three years. Abstinence from ethanol in those in whom this etiology was identified was required before surgery was offered. Several patients, however, were addicted to analgesics and efforts to correct this preoperatively were futile. Most of this group were continued on Methadone following discharge from the hospital.

### Results

Twenty-nine operations were performed on 23 patients between 1971 and 1978 for abdominal pain attributed to chronic relapsing pancreatitis. There were nine men and fourteen women, ranging in age between 27 and 74 years with a mean age of 44 years. Alcohol was the most common etiological factor as shown in Table 1.

Table 1

ETIOLOGY OF CHRONIC PANCREATITIS IN 23 PATIENTS
1971 - 1978

| *Etiology* | *No. of Patients* |
|---|---|
| Alcoholic | 17 |
| Biliary | 2 |
| Traumatic | 1 |
| Uncertain | 3 |

Pancreatic calcifications were noted on plain film of the abdomen in five patients. Although all 23 patients presented with abdominal pain, weight loss and steatorrhea were significant for six and four patients respectively. Symptomatic pleural effusions were noted in three patients and one patient had pancreatic ascites.

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ERCP was attempted in twenty of 23 patients. Successful cannulation occurred in 16 patients. Furthermore, sixteen patients had intraoperative pancreatic ductograms. In only two patients were the pancreatic ductograms in variance with ERCP findings. In both patients an abrupt cutoff of the main pancreatic duct at the junction of the body and tail of the pancreas could not be confirmed by pancreatic ductography. The collaborative value of ERCP and pancreatic ductography was best illustrated in one patient in whom separate drainage ampullae for the ducts of Wirsung and Santorini were suggested from preoperative ERCP and successfully identified by intraoperative pancreatic ductography.

Resection outnumbered drainage procedures in these 23 patients (Table 2). There were three postoperative complications; all were respiratory complications: two lobar pneumonias and one episode of adult respiratory distress syndrome requiring endotracheal intubation and mechanical ventilation. There was one early postoperative death in the oldest patient in the series whose sepsis at autopsy was attributed to Candida pyelonephritis. Long-term followup indicates relief of abdominal pain in 75 percent of patients in this series.

Table 2

OPERATIONS PERFORMED

| *Procedure* | *No.* |
|---|---|
| Distal pancreatectomy | 10 |
| Near-total pancreatectomy | 4 |
| Pancreatoduodenectomy | 2 |
| Distal pancreatectomy and pancreatojejunostomy | 4 |
| Pancreatojejunostomy | 4 |
| Sphincteroplasty | 4 |
| Sphincterotomy and pancreatic biopsy | 1 |
| Total | 29 |

## Discussion

Cattell [1] initially suggested that pancreatic ductal obstruction might be responsible for the abdominal pain associated with chronic pancreatitis. Two basic types of operations—drainage procedures and resection—have been employed to alleviate the pain associated with pancreatic ductal obstruction and inflammation. The selection of operation is determined by the pathologic anatomy of the pancreas. All of our patients since 1974 with a history compatible with recurrent pancreatitis have had ERCP attempted preoperatively to define the location and extent of ductal pathology. When ductal changes are confined to the body and tail of the pancreas, distal resection has been selected. Patients with only proximal glandular disease and a normal distal pancreas have undergone pancreatoduodenectomy. When chronic pancreatitis involves the entire gland, and is associated with a dilated ductal system, a drainage procedure is selected, but where an ectatic ductal system is encountered, near-total resection has been utilized.

The importance of intraoperative ductography can not be overemphasized. Despite the utility of ERCP, confirmation of its findings by intraoperative pancreatogram is essential. For two of our patients, normal pancreatograms obviated major resections for abrupt mid-gland obstruction diagnosed by ERCP. Furthermore, variant ductal drainage system, such as separate ampullae for the ducts of Wirsung and Santorini, have been identified by pancreatic ductograms, and sphincteroplasties of these aberrant ductal systems have been performed.

Thus, the principles involved in the surgical management of chronic relapsing pancreatitis were demonstrated in our small series of patients. Our postoperative results compare favorably with larger reported series.[2-5] Surgical management is individualized according to the site and severity of ductal pathology. The role of surgery is to alleviate the pain associated with chronic pancreatitis while preserving functioning pancreas.

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# EDITORIALS

## Have You Seen Our Hospital Lobby Lately?*

Perhaps you noticed the September 5, 1979, *Hartford Courant* headline, "Hospital Lobby Threatens Cost Control, President Says." The by-lined story by Washington correspondent Robert Waters describes a legislative briefing for "more than 200 community and business leaders invited to the White House." President Carter told them "The hospital lobby is a powerful, well-organized lobby" and "quite often the medical doctors and the people who own the hospitals are the same people."

The following week the President was in Hartford for two hours to speak to a regional meeting of older people. While many of us were fussing with security, communications and preparedness should he require our services, ironically, he was deploring the way hospital administrators and physicians fill hospital beds so they can split the profits so derived. Can it be that our President, his advisors and many other citizens do not understand the governance of their 7,000 community hospitals? Or what the "hospital lobby" is really all about?

Let's start with governance. The community hospitals are private, not-for-profit corporations, occasionally sponsored by church groups. Their Boards of Trustees are unpaid volunteers with no fiscal interest in the hospital. Sometimes one or two board members are physicians, the rest are not. The Board selects a paid, professional administrator to be the Chief Executive Officer (CEO) of the hospital. This individual, who may be called President, Executive Director, Manager, Administrator or CEO is responsible to the Board for the operation of the hospital. The Medical Staff of the hospital makes professional recommendations to the Board and CEO (often by way of a Joint Committee of some sort) but the ultimate responsibility for decisions rests with the Board. The community leaders who sit on these Boards take their role seriously. A bad fiscal judgment can be financially harmful and threaten the viability of the institution. Failure to provide state of the art resources can be harmful to the patients for whom the Board is responsible. Every decision, from which physician may have staff privileges to what piece of equipment will or will not be purchased, is their concern. Any external ruling by people not responsible for the hospital they, the Board, control is of great concern to the Board. Their collective concern voiced through their CEO's and by themselves to local legislators constitutes the real hospital lobby.

The CEO's themselves do not have the income, personal resources or corporate clout of most of the Fortune 500 top executives. The CEO's do not manage multi-national or national organizations with a wide-spectrum of local, regional and national lobbyists. They do belong (through their hospitals) to state hospital associations whose top official is usually also concerned with nursing homes and chronic disease hospitals. He would come out a poor second to most major corporate executive vice presidents in personal political influence.

Finally, there is the American Hospital Association which represents all the hospitals nationwide and has some collective influence but compared to major interest Washington lobbies it is a pigmy among giants.

So, if grass roots America, ("the electorate"), really wanted the heavy hand of government to constrain their local hospitals, the hospital lobby could be brushed aside easily. Unlike the really powerful lobbies that can have their way even if the public disapproves (like oil, or highways, or insurance companies, or some unions), the hospital lobby cannot prevail by powerful, repetitious political clout or large donations. In fact, it can only prevail under one condition, by reflecting accurately the real grass roots wish of people which in our democratic system usually also means being right *for* the people.

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*Lobby has long been a verb meaning to frequent the lobby of a legislative assembly for the purpose of influencing the members' votes. As a collective noun it means a body of lobbyists. It also refers to any kind of pressure group.

If the hospital lobby is "powerful" when it opposes the current cost-containment proposals could it mean that the *people* oppose those proposals? What evidence have we for this? As we've pointed out the men and women who run the Boards and hire the CEO's are among the most dedicated and knowledgeable citizens of their communities. Volunteers all, they have no financial interest in their hospital. It is these citizens who make the policy decisions that the CEO reflects when he opposes the cost-containment bills. It is they, because of their *local* prestige that effectively convey this message to their *local* congressmen who collectively resist the Administration's plans.

*It is* true that all of us deplore rising costs. But most citizens take a dim view that Washington D.C. plans for their hospital would work. After all, it's the same Federal Government that the President says is out of touch with the people. The hospital trustees are a more reliable barometer than D.C. bureaucrats on issues affecting local hospitals.

Who is leading the drive to contain hospital costs by fiat, not by responsible planning? Who is lobbying the most with the heaviest resources—some organized labor leaders who resent the intrusion of health care premiums at the bargaining table; some top corporate executives who feel the same way; some insurance companies who have a vested interest in the outcome of the control process? As George Will points out, if you want to understand your government, read selected portions of the D.C. telephone directory containing listings for all the organizations with titles beginning with the word "National."

The hospital lobby is local yokels, not high rollers; it has no Korean connection and certainly no mysterious controls over Congressmen. There is no hospital-depletion allowance either.

Mr. President, we hope whoever fed you the grossly inaccurate information you're citing about hospital profits and management isn't also advising on foreign affairs or defense. The truth is the people run their hospitals and the populist thing to do is to let them continue to do so because the best accountability for patient care is based on the condition that the responsible party be locally visible. "Customers" do best when they can face personally the agents of their grievance. Feed-back loops several hundred miles long are always harder to close than if they stay in the neighborhood. All of us respond a bit faster to a personal complaint than a message from HEW delivered via the Boston regional office.

Health care may require some systemization to assure access and to avoid redundancy. (Note—It is redundancy that needs to be avoided, not duplication.) But the first rule of health care is that it occurs when the patient and the health-care professional come in contact. One such setting is the hospital whose governance uniquely qualifies it to be responsive to the needs of its patients. The less tampering with this process the better.

Howard J. Wetstone, M.D.
*Director, Ambulatory Services*
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## A Vaccine Against Pneumonia

Antibiotic therapy has greatly lessened the mortality from pneumococcal infections but, seemingly, the attack rate has not been reduced. While pneumonia is a leading cause of death in the United States, this term is linked to a great and growing variety of pathogens.

The pneumonias caused by the pneumococcus are numerically overshadowed by the "atypical infections", an expression used to cover up the limitations of our knowledge. To the bacterial pneumonias and a variety of viral agents, to the mycoplasmas, rickettsias and fungi, we have added legionella and chlamydiae as causative agents. Then, among the bacteria, there are Klebsiella, staphylococci, haemophilus influenzae and a host of gram negative bacilli. The classical picture of a pneumococcal infection with lobar hepatization is relatively rare—nonetheless, in approximately twenty percent of the pneumonias the pneumococcus is still involved. The role it plays continues to be important as a cause of community-acquired bacterial disease. Hence the interest in an effective vaccine is more than justified. And such a vaccine seems to be available.

How much can we expect from a pneumonoccal vaccine? The reports from several studies are all favorable although some questions remain unanswered. The evidence of measurable and increased antibodies is not, in itself, an indication of immunity against further infection. We know, for example, that high titers of gonococcal or streptococcal antibodies do not offer such protection and that new infections take place despite their presence.

The picture is made more complicated by the large number of healthy carriers of the pneumococcus and the apparent need for some added factor to produce disease. Thus far we do not have an effective vaccine against a pathogen with a high rate of carriers, so the pneumococcal vaccine can be considered a rarity in this respect.

Pneumonia is not a reportable disease. Mortality statistics cannot convey a picture of the effectiveness of this vaccine since such statistics do not differentiate etiologically, and since pneumonia as a cause of death is often merely the final link in other chronic, progressive diseases. Though the pneumococcus may be involved, pneumonia as a so-called leading cause of death incorporates all the underlying comas, malnutritions, and advanced stages of systemic diseases.

In our environment, it will be difficult to prove the effectiveness of a pneumococcal vaccine. Still, it is available and despite a few, open questions, the evidence at this time outweighs any reservations one may have. Considering the safety record that has been reported, the new vaccine should be hailed as a potential means of reducing one type of pneumonia among those likely to become victims of this infection; namely, the elderly and those suffering from debilitating chronic ailments.

Hans H. Neumann, M.D.

# Letters to the Editor

**Letters to the Editor are welcomed and will be published, if found suitable, as space permits. They must be signed, typewritten in double spacing (including references), submitted in duplicate, must not exceed 1½ pages in length and will be subject to editing and possible abridgment. To be considered for publication, letters referring to a recent *Journal* article should be received within six weeks of the article's publication date.**

## PATIENT RECOVERY

*To the Editor:* As the President of the Connecticut Society of Physical and Rehabilitative Medicine, I wish to respond to the article by Dr. Paul W. Brown, "The Role of Motivation in Patient Recovery" in the September issue of *Connecticut Medicine.*

As a specialist dealing in Rehabilitation Medicine, I take particular exception to the remarks in the paragraph headed by the statement "Rehab is a Racket". In his zeal to expand upon his topic of motivation, Doctor Brown has made several incorrect statements. Indeed, the specialty of Physical Medicine has not missed the opportunity regarding the rehabilitation patient and the specialty continues to expand with increasing vitality. The reason for this continued expansion and demand for specialists in this field is the very fact that they do take the time to listen, educate and work with patients, families and the environment of people with long term and catastrophic illness. Although the physiatrist is uniquely qualified for this role, a rehabilitation specialist may come from other fields as well and over the past 25 years renowned specialists have come from fields such as Internal Medicine, Urology and Orthopedics.

The method in which Doctor Brown refers to "modalities" indicates that he does not have the facts or scope of knowledge necessary to make such sweeping derogatory statements. To any rehabilitation specialist, the patient is the leading member of the team approach. The patient is never passively involved but is always an active participant to the limits of his capabilities. The other members of the team, physician, nurse and therapist all seek to work with the patient to minimize impairment, decrease disability and maximize function.

I totally agree with Doctor Brown in terms of maximizing communication. Indeed, the whole concept of rehabilitation is built on communication as a foundation. Motivation is perhaps a very bad term to use for the patient with the catastrophic illness or chronic disease. A knowledge of the psychological and psychiatric factors which accompany a severe rehabilitative problem enables the specialist to work with the patient no matter what his attitude is at the time. The ultimate goal being—through education, encouragement, support—to achieve the desired participation of the patient in his own care.

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The above letter was referred to Dr. Brown who offers the following reply:

*To the Editor:* Probably Dr. Arnold is right to say that I do not have the "facts", though he did not supply any either. It would be more accurate to say that I have "opinions" and that those opinions are based on personal observation. As to "scope of knowledge" I must also admit that it, too, is limited—though based on experience in rehabilitation medicine over the past thirty-plus years. My background in this field is extensive enough to be known to most who are familiar with the specialty.

Again Dr. Arnold is correct in saying that rehabilitation specialists come from other fields of medicine. Indeed they come from *all* fields, as all physicians have as their charge, the ultimate recovery of their patients. Some, alas!, just as with physiatrists, do it well, some do it poorly, and some, not at all.

Perhaps motivation is "a very bad term" for the patient with catastrophic illness, but what stronger motivation is there than to survive? Beethoven's deafness was certainly catastrophic; it was also permanent and incurable. If there is a better term, let Dr. Arnold suggest it.

Since the paper was published I've had a mixed—and vigorous—response. Some rehabilitation specialists have agreed with my views and have ventured that I would receive strenuous protest from those of their colleagues whom my arrows stung. Dr. Arnold seems to be among the latter. As spokesman for his Society his indignation is quite understandable and should probably not be interpreted as "mea culpa".

Paul W. Brown, M.D.

*Chairman, Department of Surgery*
*St. Vincent's Medical Center*
*Bridgeport, CT*

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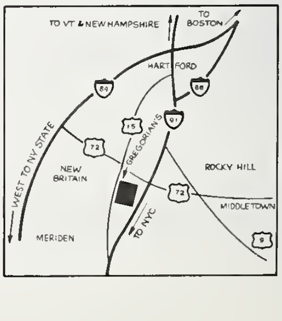
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# A New Dimension of Ethics

## ADDRESS OF HOYT D. GARDNER, M.D.
## PRESIDENT OF THE AMA

The honor of acceding to your presidency comes in a period when medicine's future seems precarious. And because it does seem precarious, we have to prepare for that future in every way.

Medicine will be challenged in all the years we can foresee. However, the American Medical Association was born to meet challenges and has developed its greatness by doing so. It is certain, and with confidence, that we can stand up to the demands of the journey ahead, as we have through most of our Association's 132-year past.

Portents are growing in every aspect of health care. To an ever-increasing degree, our destiny hinges on developments in legislation and regulation, and one could talk of those. Today, it seemed pertinent to speak in even higher terms: to talk primarily of biomedical developments in terms of their *ethical* implications for the future and to our federation.

While most of the biomedical innovations will be clearly of service to humanity, others may have consequences that are ambiguous or even downright harmful. It is the possibility of mixed or harmful results that we want to emphasize.

It is my belief that our federation should enter upon a greater role in seeing that various *forward* steps in medical ingenuity are not steps *backward* humanly and ethically. We should ponder the ultimate harvest of some of the growth in medical science and its capabilities.

A simple glance at statistics suggests the rate of that growth here in Americia. There are 200,000 research projects going on at any given time, 1,000 new technical procedures each year, several hundred new drugs annually. Each year some 17,000 medical graduates lengthen the roster of physicians, whose number in active practice now stands at 350,000. And despite federal and private cutbacks in research funding, despite a widespread cynicism or indifference toward basic research, we can expect that many new physicians will want to be pathfinders, that the momentum for pathfinding will remain strong.

Man has a deep-seated compulsion to explore and discover. There will always be men and women who seek the special exultation that Dr. Frederic Banting felt after his co-discovery of insulin. He wrote:

"These are the grandest hours of all, when the imagination is allowed to run riot on the problem that blocks the progress of research, when the hewn stones of scientific fact are turned over and over, and fitted in so that the mosaic figure of truth . . . (emerges) from the chaos." At the same time, my friends, we have to be on our guard against the possibility that the *reverse* will occur, that *chaos* will emerge from the scientific truth.

As a notably striking example, consider the possibilities of genetic maneuvering. For the purpose intended, it is well and good that this House of Delegates last December resolved that experimentation in the field of *in vitro* fertilization of human sperm and ova is ethical. Yet, test tubing can become far more than a blessing to infertile mothers. Also, cloning can become far more than a circumvention of various diseases. We have to reckon with the extreme lengths to which genetic maneuvering can be carried, including even the horrors that Aldoux Huxley envisioned in his novel, *Brave New World*. In that world, superior and inferior beings are created from biologically appropriate ova, fertilized by the appropriate sperm. Ninety-six identical twins per egg constitute the inferior, almost subhuman, beings—whose purpose on earth is to do the unskilled labor. Author Huxley's satire aside, it stands to reason that in the wrong hands and the wrong places, genetic manipulation can be corrupted.

As Huxley—a grandson and brother of eminent scientist observed: *

"We know that the pursuit of good ends does not justify the employment of bad means. But what about those situations, now of such frequent occurrence, in which good means have end results which turn out to be bad?"

---

HOYT D. GARDNER, M.D., AMA's 134th president, delivered this address at the Annual Meeting of the AMA House of Delegates, July 25, 1979, Chicago, Illinois. Dr. Gardner is a General Surgeon in private practice in Louisville, Kentucky.

* Thomas (grandfather); Sir Julian (brother)

It is easy to cite the kinds of situations to which Huxley refers. *High-minded irresponsibility* has always been with us in all fields of endeavor. Well-intentioned social planning, as in the case of health care in Britian and Canada, illustrate the ill effects that could result from similar planning in biomedicine. Let us turn to another group of ethical challenges—the kind that pit medicine's *in*finite resources against the *finite* resources of an ever more crowded world. In the face of such an imbalance, life—and the prolongation of life—might be rationed. So who would be allowed to live, and who—at least in a subtle way—would be sacrificed? What would be done with the medically hopeless? The mentally deformed? Furthermore, how would death be defined—if life is rationed? Only the respiratory apparatus was cut off in the case of Karen Ann Quinlan. In the future, what other life support and sustenance might be cut off as well? And would respiration and other means of maintaining life be terminated even in cases less hopeless than hers?

Because the economic resources for health care are widely regarded as finite, the specter of rationing medicine's growing capabilities is already visible. A *New York Times* story a year and a half ago said that according to the director of the Hasting Center—a life-sciences institute—Senator Edward Kennedy and his staff discussed with its personnel, "The issue of when and how to deny health care to some people under a system of national health insurance." The immediate concern of the Kennedy group then was the possible development of an artifical heart and the expectation that resources would be inadequate to meet the huge demand.

Another *New York Times* article said that some federal health officials have displayed a chilly attitude toward computerized axial tomography. Their distress was attributed to the cost of this relatively new breakthrough, although it has helped "thousands of people" by detecting obscure tumors, aneurysms, and other abnormalities painlessly.

On a more general level, government rationing of care would result if mandatory federal controls are imposed on hospital costs. It can ironically be said that we health care providers are our own worst enemies, in the sense that the more proficient and abailable we become *medically*, the more vulnerable we become *economically*. In the eyes of many people both inside and outside our government, the amount of *cost* seems to be a greater national concern than the amount of *care*. In such eyes, the delivery of care is apparently a basically economic *pegboard* into which all pegs should be made to fit, rather than what it actually is: an intricate swarm of ministrations to different human needs.

If we went far enough with the ideas of the economics-minded, we could say that had God made do with fewer celestial lights, He could have created heavens and earth in *five* days—and saved money. More seriously, their thinking tallies with a general and ominous mood of our time, with a tendency to regard human beings as an accumulation of objects and statistics rather than as life-size individuals. Such a mechanistic outlook is dangerous and can become terminal. It can contribute to making the present and future wonders of medicine and science less than human in their application. It can bring us closer to Huxley's Brave New World than to any dream world of science fiction. In the words of the contemporary French philosopher, Gabriel Marcel, "A technical world . . . can only end in despair."

Technology and technique must never be allowed to overwhelm a reverence for what is human in man. And that reverence is where ethics begins. We physicians are meant to be leaders, and MUST be leaders in upholding what is human. Yet, in our own way, and without realizing it, we can be as mechanistic in our approach to health-care delivery as those who see it as an economic pegboard. We can see the patient as part of the fascinating mechanics of care, instead of seeing the mechanics as part of being human. We can forget that the patient's trust in us, and in our currently beleaguered profession, is based on what's in our hearts as well as what's on our minds. *And medicine's ability to transplant hearts must include giving from our own.* As stated in the Principles of Medical Ethics of the AMA judicial Council, "The principle objective of the medical profession is to render service to humanity with full respect for the dignity of man."

*So I urge every physician in America to infuse new life and new meaning into the spirit of humanity and compassion for every patient.* In the years to come, compassion must be seen as our cornerstone for ethical responsibility. The ethics of health care are obviously subject to present rules or guidelines of law, religion and its Golden Rule, medicine itself, and custom. However, there will be new territory to stake out, grey areas to illuminate, as biomedicine moves ahead.

Because of the demographic and economic questions that are likely to be posed, there is the possibility that government will try to supply many of the answers. But many of the considerations are going to be too difficult and too pervasive for such unilateral answers. If what proves to be a wrong answer is given, we physicians would dishonor ourselves by having to abide by it.

Clashing opinions on various points of ethics can often be equally plausible and persuasive. And before answers are given on such points, a general philosophy, a basic sense of direction, should be developed. This should reflect the consensus, or at least the range of opinion, of all segments of society.

We physicians, whose sworn commitment is to do good and do no harm, must play an integral role in that evolving sense of direction. A beginning step is to cope with the ethical challenges that are already at hand. We already have a very timely vehicle for asserting ourselves ethically—a vehicle that was devised through the consensus of many groups. And that is the report of the National Commission on the Cost of Medical Care that we sponsored.

The Commission and its recommendations truly have an ethical core. For in calling for cost effectiveness and continued high quality alike in health services, they reflect a warm regard for humanity and its needs. All of us, and each of us, must take it upon ourselves to activate the Commission recommendations that have been approved by this House. We must make them an organic part of the daily consciousness and conduct of our profession.

Let me cite three of the recommendations as examples.

First, we must forcefully demonstrate that—at this time in the life of American medicine—cost awareness is a most basic form of ethical awareness. We must stimulate in our own ranks, in hospitals, and among our patients an effective realization of health-care costs and their impact on the system of care.

Second, in line with the premises of our model legislation, we must urge intensified efforts to discipline those physicians who are found to be defrauding or abusing the health-care financing or delivery system. Also, we must enable more physicians to realize they have an ethical responsibility to report a colleague's misconduct. We cannot protect a wayward colleague without violating our own sworn duty to protect the patient.

Third, we must encourage intensified research toward a basic understanding of diseases and the most appropriate treatment thereof, within the context of today's pressing need for cost containment.

In a word, our role in constructing a biomedical ethic of the future must begin now. Let me emphasize, however, that if we are to exert a maximum good influence on ethics and other growing issues, our Association must maximize its physician representation from all segments of our profession and from all states of the union. Every physician in this land has a *membership* in the *problems* that the AMA copes with in his or her behalf. An ethical problem can arise in any physician's routine practice, on a day that dawned like any other. And thus it was in a memorable episode that I especially like to single out, because it occurred in my own state.

Dr. Ephraim McDowell expected nothing but routine when summoned one day in 1809 to the distant cabin of Mrs. Thomas Crawford. When he arrived—a coonskin-capped, lanky man on horseback—he was told simply that she was impeded in giving birth. He found, however, that she was not pregnant. What she had was a huge tumor of the ovaries.

On Christmas Day, in his own town of Danville, Kentucky, he undertook what no physician before him had dared to do. He performed the first ovariotomy, opening the way for all types of abdominal surgery. Had the outcome been fatal, an excited mob waiting outside would have hanged Dr. McDowell as an ungodly murderer, despite the certainty that Mrs. Crawford would have died *without* the surgery. But she survived and the crowd cheered. That's how ethics were decided on the old frontier. As a matter of fact, the patient lived to a ripe old age.

The frontier is long gone, and we physicians now are one great community. It is for this whole interrelated, interdependent community that our federation acts. In the field of ethics, the activity has been reflected in the work of the AMA Judicial Council and ethics committees at state and local levels. It has been reflected in our stimulation of peer review, tissue committees, medical audits, and continuing medical education—all of which, in contributing to physician competence, serve ethics as well. And not least, our active ethical concern is reflected in our forceful stand against any legistative, regulative, or other steps that would set off the rationing of care.

From the AMA's founding in 1847, primarily to reform medical education, our Association has kept adding new dimensions to our sense of commitment. So my call for a *fuller* ethical dimension is true to our historic character and principles. Such a commitment is especially needed today, in the face of a deterioration of ethics in many aspects of our national life. Through that commitment, we can achieve a better climate for the future growth of biomedicine and for public confidence in what that field can generate. We can help bring out the best in the medical and scientific mind, by smoothing its way in terms of the human heart. We can help medicine journey onward in the spirit Walter Lippmann extolled, in a tribute to aviator Amelia Earhart. He said:

"The best things of mankind are . . . things that are undertaken because someone is moved—by curiosity, the love of excellence, a point of honor, the compulsion to invent or to understand. In such persons mankind overcomes the inertia which would keep it earthbound forever in its habitual ways. . . And what they prove to themselves and to others is that man is no mere creature of his habits, no mere cog in the collective machine . . . but that in the dust of which he is made there is also fire—lighted now and then by great winds from the sky."

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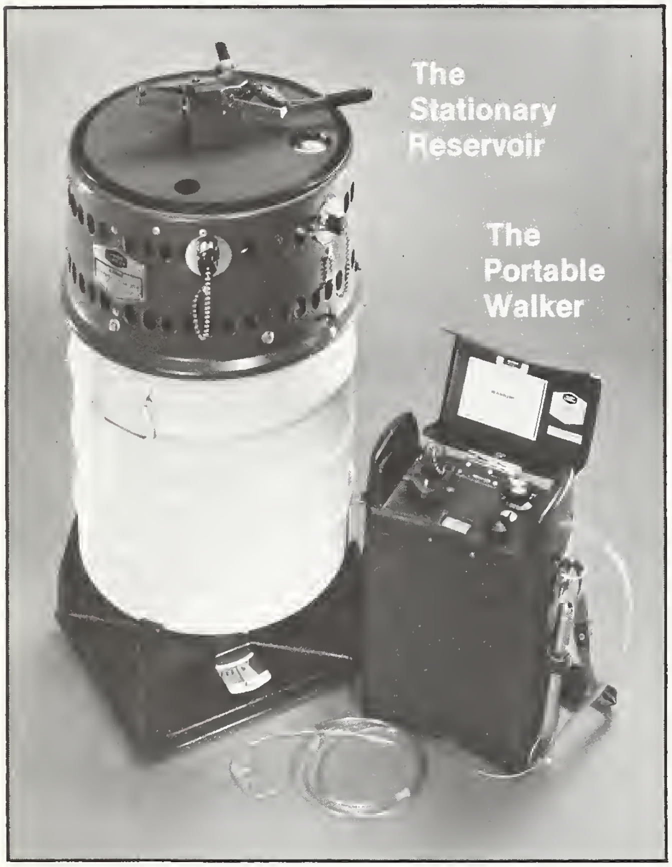

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# An Oncology Unit Is Not for Every Cancer Patient

BERNARD V. STRAUSS, M.D.

**ABSTRACT—Patients on an Oncology Unit are especially vulnerable to anxiety and depression. How the unit is organized and conducted will substantially affect the nature and extent of the patient's adjustment to his illness. This is the concern which the present paper seeks to address.**

There are a variety of psychological pluses, psychological minuses, cautions and recommendations which should be kept in mind in the planning and operation of an Oncology Unit. Of fundamental concern is the need to avoid the injustice so frequently involved in following all-encompassing rigid rules and regulations—without regard for the appropriateness of the fit between the person and the circumstances. I would emphasize the paramount importance of concern for the individual patient, for his rights and his privacy. Concurrently, it must also be recognized that there are times when it is necessary to forego some aspect of privacy in order to care for some more immediate, pressing and perhaps life-threatening need. The objective to individualize should be the over-riding concern.

All of this has, of course, a strong bearing on the question of the desirability of an oncology unit where all cancer patients are put together on one particular floor—in either private, semi-private or multi-bedded rooms. While the ambiance and method of operation of the unit importantly affect its suitability for any particular cancer patient, it will, nevertheless, remain true that for some it will be helpful and for others, distressing. The physician should bend every effort to determine under what conditions his particular patient is likely to fare best. There is little doubt that some will do better, will retain their self-respect and self-esteem better, if they are permitted to "keep their troubles to themselves;" while others strongly need, welcome and benefit from support, presence and social interchange with fellow patients.

### Psychological Pluses

1. Patients are less likely to feel alone and singled out for their misfortune. They are all in the same boat.
2. It will be both apparent and purposefully described that the Unit has immediately available all of the latest and best equipment and devices for the treatment of the patients' illness. This can't help but be encouraging.
3. The concentration of specially trained experts and equipment will also be evident, highlighted, and encouraging.
4. Opportunity to see other patients improve and go home from the Unit will be helpful.
5. For those who want, need, and can use it—specialized group therapy and individual counselling should be made available. Here one must proceed with caution.
6. Counselling for concerned families—aid in dealing with ambivalence. These measures are often essential; the results feed back to the patient and affect his welfare.
7. A planned Unit atmosphere—banish gloom and doom; promote some interest and wherever possible some "doing," some activity, some participation, and something to look forward to; something to indicate "it's not all over."
8. For the patients to have an opportunity to see the Unit as a training center will give them confidence that they are receiving the best of care from the best qualified care-givers.
9. There will be opportunity for a specially-oriented kind of team and group exchanges regarding all aspects of the treatment and responses of the patients, their illnesses, and their interaction with relatives.

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BERNARD V. STRAUSS, M.D., Chairman, Department of Psychiatry, Danbury Hospital; Lecturer in Psychiatry Yale University School of Medicine.

### Psychological Minuses

1. Inevitable recognition of the nature and type of clientele of the Unit. For those for whom preparation and disclosure were appropriate this is not so much of a problem; for others it can be a devastating blow. For some, preparation may succeed in mitigating but may fall short of removing the dire foreboding.
2. For relatives a visit to the Unit underscores the plight of patient and family. If possible, relatives should have an opportunity where appropriate to see some recovering and "going home" patients.
3. As is true with many emotions, it is unfortunately true in this situation that the discouragement and depression of some may well be contagious to others. In this respect, the general ward atmosphere, group sharing and airing can help. There must be provision for immediate help for those who will break down once talking about their troubles weakens their defenses.
4. Assignment to an Oncology Unit will challenge the privacy and independence of those patients who treasure these qualities and strongly defend them. Their very integrity is threatened by the apprehension of imminent invasion of their personal physical and psychological privacy.
5. Just a historical note which dramatically highlights the kind of thing to be avoided. In New York, years ago, there used to be a "Home for Incurables," a "Hospital for the Crippled and Disabled," and a "Brooklyn Cancer Institute." All labels of horror, which did no one any good. In addition to name changes, we now need to ensure against scuttlebutt talk about "admission equals cancer equals death." Cured dischargees should be prominent; "transferees" should be unobtrusive.

### Cautions

1. There should be careful preadmission screening. Those who depend absolutely on denial should be excluded from the Unit. Wherever honestly possible, an upbeat attitude should be conveyed.
2. Disclosure of diagnosis and/or prognosis is either good, bad, or indifferent—depending on timing, what is disclosed, how it is disclosed, and to whom it is being disclosed: the "to whom" should control the what and the how. This is much easier said than done. It requires concern with much personal detail not ordinarily considered where the disease is prominent and threatening.

### Recommendation

Much of the recommendation that we will list below would, of course, be superfluous if it were not necessary to deal with patients and their families as the human beings they are; with the limitless variety of unpredictable responses, possible misinterpretations, positive and negative identifications, projections, and the like.

1. Except for emergencies, preadmission psychiatric screening should have a three-fold objective:
   1:1. Determine suitability of patients for the Unit.
   1:2. Enhance preparation of suitable patients (acceptance of need, allaying of anticipatory apprehensions).
   1:3. As indicated, preparation of a plan for in-hospital psychotherapy, group participation, psychotropic medication, counselling of relatives, etc.
2. Routine and regular Unit coverage by a consultation-liaison psychiatrist. He should have an opportunity to get to know all of the patients. He can then allocate his time in accordance with an assessment of individual patient's needs. The psychiatrist will require assistance by a specially trained psychiatric social worker.
3. Inexpert psychological probing should be strictly prohibited. Just as a proper dosage of medicine properly administered can be lifesaving, while an improper dosage improperly administered can be fatal; so it is with probing. However well intentioned it may be, inexpert delving and urging may shatter feeble defenses and precipitate a serious breakdown. When in doubt, don't push. Awareness of Body Image Concept can be helpful in understanding the protective, unconscious, mental dynamisms patients whose bodies are under assault are likely to use, e.g., projection(it is not happening to me, it is happening to them); depression (life is worthless without my stomach, kidney, or leg, etc.); nihilistic delusions (my whole insides are rotting); denial (I am fine, never felt better, ready to go to work today); regression (I'm helpless, expect nothing from me, help me, you are my only hope).
4. Whenever possible, an effort should be made to have some "sure to get well-enough to go home" patients on the Unit. Again, whenever possible, necessary "transfers" should be unobtrusively accomplished.
5. There is much opportunity for psychologically oriented research on such a Unit; not only in terms of patients' and families' reactions to the patient's illness; but also in terms of the patients' life circumstances and emotional status prior to and about the time of onset of the illness.

The nature of the disease of cancer and the way people tend to react to it and even to the word itself, make it especially important that the physician and his associates be alert and appropriately sensitive and responsive to his patients' and their families' practical, social and psychological concerns. Placement on an Oncology Unit should not be automatic. It should be selected for its appropriateness for the particular patient's needs.

# Creating the Pneumococcal Pneumonia Vaccine: A Hundred-Year Story

MICHELE McGANN STEEGE

With the Fall immunization season upon us, many physicians in Connecticut are intensifying their effort to vaccinate their chronically-ill patients and those over 50 with pneumococcal pneumonia vaccine.

In the 18 months since the introduction of 'Pneumovax' (Pneumococcal Vaccine, Polyvalent, MSD) by Merck Sharp & Dohme, more than three million persons have been vaccinated nationwide. Group vaccination programs have taken place in Connecticut and a number of other states including Massachusetts, New York, New Jersey, Pennsylvania, Alabama, Wisconsin, and Ohio (which in the Fall of 1978 announced plans to vaccinate its 60,000 nursing home residents). Under the supervision of the Massachusetts Department of Public Health, 'Pneumovax' has been administered to over 13,000 elderly individuals in a statewide program.

While the licensing of 'Pneumovax' in November 1977 was called by the American Medical Association "perhaps the most important medical development" of the year, the vaccine's history can actually be traced back almost 100 years.

The story is marked both by major advances and by major reverses. In fact, precursor pneumococcal pneumonia vaccines, far less complex than 'Pneumovax', were actually available to physicians in the late 1940's, but were discontinued from lack of use following introduction of penicillin and the other antibiotics.

From that time until only recently, the prevailing medical belief was that antibiotics were almost totally effective in controlling pneumococcal pneumonia.

The way in which this belief was disproved so that research and development could move forward, culminating in the sophisticated vaccine of today, is one of the more interesting and unusual aspects of the story.

Today it is recognized that pneumococcal pneumonia is still a major health problem throughout the world. Experts estimate that in the U.S. alone, there may be as many as 200,000 to 1,000,000 cases of pneumococcal pneumonia a year, resulting in 13,000 to 66,000 deaths a year, despite the availability of antibiotics. Limited data also indicate that 25 percent or more of those who contract pneumococcal pneumonia develop bacteremia. About 17 percent of these bacteremic patients die in spite of treatment with available antibiotics, and the death rate exceeds 25 percent in bacteremic patients 50 years of age and over, and in those with certain chronic illnesses.

'Pneumovax' has been shown to be at least 90 percent effective in immunizing against 14 types of pneumococcal bacteria. These 14 pneumococcal types are responsible for over 80 percent of all pneumococcal pneumonia cases in the U.S.

The history of the vaccine dates back to 1881 when both Louis Pasteur and George M. Sternberg isolated the pneumococcus in independent research. This set the stage for two German physicians, George and Felix Klemperer, to prove ten years later that a vaccine made of whole pneumococci would produce immunity to the bacteria in rabbits.

In 1911 the first attempts to immunize people against pneumococcal pneumonia were carried out in the mines of South Africa (where Merck Sharp & Dohme scientists would return in the early 1970's). Here the gold and diamond miners are exposed to extreme heat and humidity in the mines and to close living quarters in dormitories. These factors lead to a very high incidence of pneumococcal pneumonia. In the 1911 South African trial, British bacteriologist Sir Almroth Wright and his team vaccinated gold and diamond miners with the whole killed pneumococci. These scientists failed to get conclusive results, probably because they did not take into account the different strains of the pneumococcus. Subsequent research has shown that antibodies to one pneumococcal strain are not usually effective against other strains.

A shift in the focus of the vaccine's development took place in 1927 when two German researchers, Wolfgang A. Casper and Oscar Schiemann, found that the polysaccharide material that forms the capsule surrounding the pneumococcus caused animals to produce antibodies to the bacteria. In 1930 Thomas Francis, Jr., and William S. Tillett, two American scientists, showed that pneumococcal polysaccharides induced antibodies in patients recovering from pneumococcal pneumonia. Over the next eight years, Dr. Maxwell Finland and his teams

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MICHELE McGANN STEEGE is a Philadelphia-based science and health writer who has been published extensively in the University of Pennsylvania publications, *Health Affairs, Pennsylvania Gazette*, and *Almanac*. In addition, she has prepared written materials for the Wistar Institute, the University of Pennsylvania Museum, and the Pennsylvania Mental Health Association, and has written for *Philadelphia, Discover*, and *Business Week* Magazines. This article was prepared under the auspices of Merck Sharp & Dohme in West Point, Pennsylvania.

immunized healthy people with the polysaccharide material and developed the first data on polysaccharide dosages needed to induce antibodies. This series of trials was particularly important since people vaccinated with the polysaccharide developed the antibodies necessary to prevent the disease, but did not develop pneumococcal pneumonia itself.

In the next phase of development, scientists conducted large-scale trials with vaccines combining polysaccharides from more than one strain of pneumococci. When Dr. Lloyd D. Felton vaccinated 60,000 men with two types of polysaccharides, his results, reported in 1938, strongly suggested that the vaccine was effective in preventing infection caused by the two types of pneumococci. Conclusive evidence came in 1945 when Dr. Colin M. MacLeod reported on a test conducted during an epidemic of pneumococcal pneumonia at an Army Air Force Technical Training School. His vaccine, containing polysaccharide material from four types of pneumococci, prevented these types of pneumococcal pneumonia. This test also showed that the vaccine protected people only against the types of pneumococci whose polysaccharides it included. More data were offered when Dr. Paul Kaufman reported in 1947 on a six-year study of 5,000 men and women 50 or over. He demonstrated that a vaccine with three pneumococcal polysaccharides reduced the incidence of those types of pneumonia, and subsequent bacteremia, by 90 percent. Dr. Michael Heidelberger and associates later proved that one vaccine could successfully contain up to six pneumococcal polysaccharides and that significant antibody levels lasted for five to eight years after the injection.

With this research to back it up, two six-valent pneumococcal polysaccharide vaccines were licensed and marketed from 1945 to 1947. But since the newly introduced penicillin and other antibiotics were effective in treating the disease, the vaccines were rarely used, and the manufacturer discontinued production.

The vaccines would have become an historical aside, except for Dr. Robert Austrian, currently Chairman of the Department of Research Medicine at the University of Pennsylvania. In 1952 he began a ten-year study of pneumococcal infection in King's County Hospital in New York City where, according to the admissions records, there were only three or four cases of pneumococcal infection a year. Using bacteriologic techniques common before antimicrobial drugs became available, Dr. Austrian turned up more than 2,500 cases over the ten-year study period. The hospital was actually admitting about as many people for pneumococcal infection as it had before the introduction of antibiotics. Moreover, the death rate from uncomplicated bacteremic pneumococcal pneumonia treated with penicillin or with other antibiotics was 17 to 18 percent. In patients 50 and over and in those with underlying systemic illness, the date rate, even with antibiotic treatment, exceeded 25 percent.

Dr. Austrian's work was initially met with a great deal of skepticism. As one of his colleagues confessed at a recent symposium on pneumonia, "I can't resist indicating that about 20 years ago I introduced Dr. Austrian to my laboratory group. . . . Though I thought I had given a glowing introduction, my own doubts about the importance of the pneumococcus must have been apparent because when Dr. Austrian got up he said, 'This is the first time I have been introduced as an anachronism.' This work has proven me wrong."

Dr. Austrian, who published his results in 1964, says of his push for the vaccine, "It was the logical thing to do. It was as much a problem of human behavior and of trying to convince others that antibiotics were not doing the complete job as it was of medical research."

In 1967, the Infectious Disease Branch of the National Institute of Allergy and Infectious Diseases began support of a major effort to develop such a vaccine. The objective was to determine the types of pneumococci responsible for most pneumococcal infections and to prepare polysaccharides from these types for use in suitable vaccines. Information from this and earlier studies was used to pick the types of pneumococcal polysaccharides to be included in the U.S. vaccine.

Dr. Austrian played a major role in all aspects of this program and later provided advice and consultation to scientists of the Merck Sharp & Dohme Research Laboratories in the development of 'Pneumovax'.

Scientists at the Merck Sharp & Dohme Research Laboratories began work on the development of a pneumococcal pneumonia vaccine in 1970.

The seven-year Merck research and development effort involved scientists and technical specialists in the company's research laboratories both in Rahway, New Jersey, and in West Point, Pennsylvania, under the overall direction of Dr. Maurice R. Hilleman, Vice President and Director of Virus and Cell Biology Research.

Committing to development of pneumococcal vaccine was a logical step for Merck. The company had played key roles in the development of measles, rubella, and mumps vaccines and was the first pharmaceutical manufacturer to make an influenza vaccine for humans. Merck also developed a technique called lyophilization, or freeze-drying, which has made it possible to ship vaccines all over the world.

Using seed stock from Robert Austrian's laboratory at the University of Pennsylvania, the Merck scientists set about growing the bacteria and working out ways to make them produce enough of the polysaccharide capsule material for isolation. By manipulating nutritional content of the growth media, and incubation times and temperatures, they were able to work out the most fruitful growing conditions for each of the many strains of pneumococci that would ultimately be used in the vaccine.

The researchers then isolated the polysaccharides and developed a process for purifying them. Complex tests were performed at each stage of the work to assure that the polysaccharides were chemically correct and pure.

The Merck researchers then formulated the purified polysaccharides into vaccines, established appropriate methodologies to control test them, organized and monitored all human clinical studies, and performed all serological assays to measure antibody responses.

The researchers formulated vaccines containing polysaccharides from six pneumococcal types, from 12 types, and from 14 types.

Once the vaccines passed the control tests, clinical trials were set up to determine whether the vaccines would trigger antibody production in people to each pneumococcal type, and whether the vaccines would reduce the incidence of pneumococcal pneumonia in susceptible populations.

Clinical trials with Merck pneumococcal vaccines began in early 1973. Following the tradition of Sir Almroth Wright, Merck researchers conducted major studies in the gold miners of South Africa.

To the gold mines in Transvaal, South Africa, young men come regularly from distant areas of that country and from neighboring countries such as Malawi and Mozambique, seeking reliable income and a place to live. Since they are new to the area, they have little immunity to many of the prevalent diseases, including the local strains of pneumococcal pneumonia.

They work long days drilling ore from veins as far as two miles underground, where the temperature is 80 degrees, the humidity is 100 percent, and the rock temperature is as high as 125 degrees. After a day's work under these extremes of heat and humidity, the miners return to dormitories where they live in close contact with others who may harbor many different strains of the pneumococcal bacteria.

Under these conditions, the miners have traditionally had a very high incidence of pneumococcal pneumonia and so have been a logical group for testing of pneumococcal vaccines. The Merck trials were conducted with 4,694 novice miners who volunteered for the tests. In one trial, 983 novice miners received a vaccine containing six pneumococcal polysaccharides; 2,036 miners served as controls. This trial showed a 76 percent reduction in pneumococcal pneumonia cases of the six types included in the vaccine. In a second trial, 540 miners received a 12-valent pneumococcal polysaccharide vaccine, with 1,135 miners serving as controls. The result: a 92 percent reduction in the incidence of pneumonia caused by the 12 pneumococcal types represented in the vaccine.

The trials in South Africa were only one set among several. By late 1977, tests had been carried out in close to 13,000 adults and children in the U.S. and in areas overseas where people have a high vulnerability to pneumococcal disease, including Chile and New Guinea.

While testing was underway, Merck scientists were facing a second challenge—developing a process for large-scale production of the vaccine.

With guidance from Dr. Austrian, Merck scientists determined that the final vaccine would contain 14 pneumococcal polysaccharides representing the strains responsible for over 80 percent of pneumococcal disease in the U.S.

Fourteen parallel production processes had to be developed, one for each strain of polysaccharide to be incorporated in the vaccine.

A new manufacturing facility was built at the company's headquarters in West Point, Pennsylvania, to house the equipment needed for the various stages of vaccine production—fermentation, centrifugation, filtration. During the final phase of the program, researchers and production specialists were working 24-hour stagger shifts, seven days a week to complete the project.

In the long and complex vaccine production process, the bacteria are grown first in small culture dishes, then in flasks and tanks of gradually increasing size. In the final part of the growth cycle, the bacteria are grown in 800-liter fermentation tanks. Technicians monitor the growth rates and condition of the bacteria throughout.

When the growth cycle is completed, the bacteria are killed with phenol. The killed bacteria are removed and the capsule material is treated chemically and purified further through centrifugation until only the highly purified polysaccharide remains. This is dried to a white powder, which is carefully tested to make sure it has the correct chemical composition. It is then combined with the other polysaccharides that have gone through similar tests, diluted to the proper strength, filtered for sterility, and tested again. The vaccine is formulated so that each 0.5 ml. dose contains 50 micrograms of each of the 14 types of polysaccharide.

Samples from each lot of filled vaccine are sent to the Bureau of Biologics of the U.S. Food and Drug Administration for certification testing; more than 100 specifications for chemical identity, purity and sterility must be met before the Bureau approves release of the lot.

The vaccine is recommended for people who are at increased risk from pneumococcal pneumonia, including people with chronic heart, lung, or kidney diseases, diabetes, and metabolic disorders; people in chronic care facilities; people recovering from severe illness; and people 50 years of age and over. The vaccine is not recommended for children under two years of age since they do not develop enough antibodies to some of the pneumococcal types.

Researchers are still studying how long the protective effect of the vaccine lasts, but it has been shown in previous studies with other pneumococcal polysaccharide vaccines that antibody may persist for as long as five years. Available data suggest that revaccination should not take place for at least three years so as to minimize the frequency and severity of local reactions, especially in people who have retained high antibody levels. Long-term study of this is continuing.

Most patients tolerate the vaccine well, with the most common side effects being local erythema and soreness at the injection site, usually subsiding within 48 hours. Low-grade fever (less than 100.9° F) occurs occasionally and is usually confined to the 24-hour period following vaccination. Although rare, fever over 102° F has been reported. Reactions of greater severity, duration, or extent are unusual. Rarely, anaphylactoid reactions have been reported. The vaccine should not be given to pregnant women as the possible effects on fetal development are unknown. The vaccine should be used with caution in patients with severely compromised heart or lung function in whom a systemic reaction would pose a significant risk and also in patients who have had episodes of pneumococcal pneumonia or other pneumococcal infection in the preceding three years.

While pneumonia is often thought of as a winter disease, a significant number of cases occur year round. According to figures for 1977 from the National Center for Health Statistics, close to 24 percent of all cases occurred in January, February, and March; over 19 percent in April, May, and June; close to 20 percent in July, August, and September; and close to 37 percent in October, November, and December. Vaccination in summer and fall should be considered so that eligible patients will be protected before the late fall and winter "cold" season and will not have to wait until respiratory or other infections clear up.

Looking to the future, a number of further uses for the vaccine are being investigated.

Early studies suggest that the vaccine is effective in preventing pneumococcal pneumonia in victims of sickle cell anemia and in those who have defective spleens or have had their spleens removed. Since the spleen acts as a staging area for many of the body's defense mechanisms which fight pneumococcal bacteria, these patients are particularly vulnerable to pneumococcal pneumonia and tend to get severe cases.

The National Institute of Allergy and Infectious Diseases is coordinating a number of studies of the vaccine in victims of sickle cell anemia and in people without spleens; this work is underway primarily in the U.S. and also in Canada and Jamaica. It is expected that information gained from these studies will enable advisory groups such as the Advisory Committee on Immunization of the Public Health Service and the Redbook Committee of the American Academy of Pediatrics to make recommendations on the use of the vaccine for these groups.

Another area of research is the use of the vaccine to prevent otitis media in children. By age ten, 75 percent of all children have had this serious and common ear infection.

A major study sponsored by Merck that will eventually include about 1,500 children under the age of seven is now underway in Finland, where there is a very high incidence of otitis media. There are also studies under the sponsorship of the National Institute of Allergy and Infectious Diseases being conducted in the U.S. Data from these studies will be available within the next one to two years.

The National Institute of Allergy and Infectious Diseases is also coordinating studies on the use of pneumococcal vaccine in other conditions that predispose people to pneumococcal infections, such as Hodgkin's disease, multiple myeloma, leukemia, nephrotic syndrome of childhood, lupus erythematosus, renal insufficiency, alcoholic cirrhosis, and Cooley's anemia.

"We're interested in coordinating and working with physicians to do anything we can to expand the use of pneumococcal vaccines into patient populations with additional conditions in which we think it might be useful," says Dr. James C. Hill, Bacterial Vaccines Program Officer of the National Institute of Allergy and Infectious Diseases.

Research has demonstrated that the vaccine has the potential to save thousands of lives a year that are now being lost to pneumococcal pneumonia.

Major economic benefits may also be derived from development of the vaccine. About two-thirds of all patients with pneumococcal pneumonia require hospitalization, and their average stay in the hospital is 9.6 days. About three-fourths of pneumococcal pneumonia patients lose about 10 working days. Use of the vaccine in the recommended groups can be expected to make important reductions in hospitalizations and lost working time now attributable to pneumococcal pneumonia.

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EDITOR'S NOTE: This article was invited by the editor because of Merck's role in the vaccine's development. In September of this year, Lederle Laboratories introduced a pneumococcal vaccine that is virtually identical to Merck's.

# Influenza Vaccine—1979

CENTER FOR DISEASE CONTROL

H.E.W., Public Health Service, Atlanta, Ga.

## Introduction

Influenza virus infections occur every year in the United States, but they vary greatly in incidence and geographic distribution. Infections may be asymptomatic, or they may produce a spectrum of manifestations, ranging from mild upper respiratory infection to pneumonia and death. Influenza viruses A and B are responsible for only a portion of all respiratory disease. However, they are unique in their ability to cause periodic widespread outbreaks of febrile respiratory disease in both adults and children. Influenza epidemics are frequently associated with deaths in excess of the number normally expected. During the period from 1968 to 1979, more than 150,000 excess deaths are estimated to have occurred during epidemics of influenza A in the United States.

Efforts to prevent or control influenza in the United States have been aimed at protecting those at greatest risk of serious illness or death. Observations during influenza epidemics have indicated that influenza-related deaths occur primarily among chronically ill adults and children and in older persons, especially those over age 65. Therefore, annual vaccination is recommended for these "high-risk" individuals.

Influenza A viruses can be classified into subtypes on the basis of 2 antigens: hemagglutinin (H) and neuraminidase (N). Four subtypes of hemagglutinin (HO-H3) and 2 subtypes of neuraminidase (N1, N2) are recognized among viruses causing widespread disease among humans. Immunity to these antigens reduces the likelihood of infection and reduces the severity of disease in infected persons. However, there may be sufficient antigenic variation within the same subtype over time (antigenic drift) that infection or immunization with 1 strain may not induce immunity to distantly related strains. As a consequence, the antigenic composition of the most current strains is considered in selecting the virus strain(s) to be included in the vaccine.

The predominant influenza strain in the United States during 1978-79 was A/Brazil/78—a variant of the H1N1 prototype A/USSR/77. This strain caused outbreaks in schools, colleges, and military bases, as had been the case with the prototype strain. People over 25 years of age generally were not affected, presumably because of previous infection with antigenically related strains that had circulated throughout the world in the early 1950s. Strains of the subtype H3N2 were not isolated in the United States, but other countries reported the isolation of both H1N1 and H3N2 strains. Since it is uncertain which strain will predominate in the future, continued circulation of strains related to A/Texas/77 (H3N2) and A/Brazil/78 (H1N1) must be anticipated.

Outbreaks caused by influenza B viruses occur less frequently than influenza A epidemics, but influenza B infection can also cause serious illness or death. Influenza B viruses have shown much more antigenic stability than influenza A viruses. Strains of influenza B that were isolated in 1978 and 1979 in the United States and elsewhere resembled the B/Hong Kong/5/72 virus.

## Influenza Virus Vaccine for 1979-80

Influenza vaccine for 1979-80* (See Table 1) will consist of inactivated trivalent preparations of antigens representative of influenza viruses expected to be prevalent: A/Brazil/78 (H1N1), A/Texas/77 (H3N2), and B/Hong Kong/72. The formulation will contain 7 micrograms of hemagglutinin of each antigen in each 0.5 ml dose. Persons 27 years and older will require only 1 dose. Because of lack of previous contact with H1N1 strains, persons less than 27 who did not receive at least 1 dose of the 1978-79 trivalent vaccine will require 2 doses of the 1979-80 vaccine. Those who received the 1978-79 vaccine will require only 1 dose. The vaccine will be available as whole

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virion (whole-virus) and subviron (split-virus) preparations. Based on past data, split-virus vaccines have been associated with somewhat fewer side effects than whole-virus vaccines in children. Thus, only split-virus vaccines are recommended for persons less than 13 years of age. The vaccines prepared for the 1978-79 respiratory disease season contained A/USSR/77 as the H1N1 component. Because of the antigenic similarities between the A/USSR/77 and the A/Brazil/78 strains, the stocks of vaccine remaining from last year may be used, until the expiration date, according to the instructions on the package insert.

## Vaccine Usage

### General Recommendations

Annual vaccination is strongly recommended for all individuals at increased risk of adverse consequences from infections of the lower respiratory tract. Conditions predisposing to such risk include (1) acquired or congenital heart disease associated with altered circulatory dynamics, actual or potential (for example, mitral stenosis, congestive heart failure, or pulmonary vascular overload); (2) any chronic disorder with compromised pulmonary function, such as chronic obstructive pulmonary disease, bronchiectasis, tuberculosis, severe asthma, cystic fibrosis, neuromuscular and orthopedic disorders with impaired ventilation, and residual pulmonary dysplasia following the neonatal respiratory distress syndrome; (3) chronic renal disease with azotemia or the nephrotic syndrome; (4) diabetes mellitus and other metabolic diseases with increased susceptibility to infection; (5) chronic, severe anemia, such as sickle cell disease; and (6) conditions which compromise the immune mechanism, including certain malignancies and immunosuppressive therapy.

Vaccination is also recommended for older persons, particularly those over age 65, because excess mortality in influenza outbreaks occurs in this age group.

In considering vaccination of persons who provide essential community services or who may be at increased risk of exposure, such as medical care personnel, the inherent benefits, risks, and cost of vaccination should be taken into account.

Table I summarizes vaccine and dosage recommendations by age group for 1979-80.

### Use in Pregnancy

Although the issue has been much discussed, only in the pandemics of 1918-19 and 1957-58 has strong evidence appeared relating influenza infections with increased maternal mortality. Although several studies have reported an increased risk of congenital malformations and childhood leukemia among children born to women who had influenza infection during pregnancy, other studies have not shown an increased risk; the issue is not settled.

Physicians prudently limit prescription of drugs and biologics for pregnant women. However, no evidence has been presented to suggest that influenza vaccination of pregnant women poses any special maternal or fetal risk. Futhermore, because influenza vaccine is an inactivated viral preparation, it does not share the theoretical risks that impel caution in the use of live virus vaccines. Taking the above uncertainties into account, physicians should evaluate pregnant women for influenza immunization according to the same criteria applied to other persons. (See VACCINE USAGE—General Recommendations)

## Side Effects and Adverse Reactions

Recent influenza virus vaccines have been associated with few side effects. Local reactions, consisting of redness and induration at the site of injection lasting 1 or 2 days, have been observed in less than one-third of vaccinees. Three types of systemic reactions to influenza vaccines have been described.

Table 1

INFLUENZA VACCINE* DOSAGE, BY AGE, 1979-80

| *Age group* | *Product* | *Dosage (ml)* | *Number of doses* |
|---|---|---|---|
| 27 years and older | whole virion (whole virus) or subvirion (split virus) | 0.5 | 1 |
| 13-26 years | whole virion (whole virus) or subvirion (split virus) | 0.5 | 2** |
| 3-12 years | subvirion (split virus) | 0.5 | 2** |
| 6-35 months*** | subvirion (split virus) | 0.25 | 2** |

*Contains 7 *ug* each of A/Brazil/78, A/Texas/77, B/Hong Kong/72 hemagglutinin antigens in each 0.5 ml.

**4 weeks or more between doses; both doses essential for good protection, unless the individual received at least 1 dose of 1978-79 vaccine.

***Based on limited data. Since the likelihood of febrile convulsions are greater in this age group, special care should be taken in weighing relative risks and benefits.

1. Fever, malaise, myalgia, and other systemic symptoms of toxicity, although infrequent, occur more often in children and others who have had no experience with influenza viruses containing the vaccine antigen(s). These reactions, which begin 6-12 hours after vaccination and persist 1-2 days, are usually attributed to the influenza virus itself (even though it is inactivated) and constitute most of the side effects of influenza vaccination.

2. Immediate—presumably allergic—responses, such as flare and wheal or various respiratory expressions of hypersensitivity occur extremely rarely after influenza vaccination. They probably derive from sensitivity to some vaccine component, most likely residual egg protein. Although current influenza vaccines contain only a small quantity of egg protein, on rare occasions they can provoke hypersensitivity reactions. Individuals with anaphylactic hypersensitivity to eggs should not be given influenza vaccine. This would include persons who, upon ingestion of eggs, develop swelling of the lips or tongue or who experience acute respiratory distress or collapse.

3. Guillain-Barre' syndrome (GBS) is an uncommon illness characterized by ascending paralysis which is usually self-limited and reversible. Though most persons with GBS recover without residual weakness, approximately 5% of cases are fatal. Before 1976, no association of GBS with influenza vaccination was recognized. That year, however, GBS appeared in excess frequency among persons who had received the A/New Jersey/76 influenza vaccine. For the 10 weeks following vaccination the excess risk was found to be approximately 10 cases of GBS for every million persons vaccinated—an incidence 5-6 times higher than that in unvaccinated persons. Younger persons (under 25 years) had a lower relative risk than others and also had a lower case-fatality rate. Preliminary analysis of data from GBS surveillance during the 1978-79 influenza season suggests that, in contrast to the 1976 situation, the risk of GBS in recipients of the 1978-79 vaccine was not significantly higher than that in non-vaccinees. Nonetheless, persons who receive influenza vaccine should be made aware of this possible risk as compared with the risk of influenza and its complications.

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**CONTRAINDICATIONS:** Because of the quinine content, Quinamm is contraindicated in women of childbearing potential, in pregnancy, in patients with known quinine sensitivity, and in patients with glucose-6-phosphate dehydrogenase deficiency. Hemolysis (with the potential for hemolytic anemia) has been associated with a G-6-PD deficiency in patients taking quinine.

**PRECAUTIONS:** Thrombocytopenic purpura may follow the administration of quinine in highly sensitive patients. Recovery will follow withdrawal of the medication. Cinchona alkaloids, including quinine, have the potential to depress the hepatic enzyme system that synthesizes the vitamin K-dependent factors. The resulting hypoprothrombinemic effect may enhance the action of warfarin and other oral anticoagulants.

**ADVERSE REACTIONS:** Aminophylline may produce intestinal cramps in some instances, and quinine may produce symptoms of cinchonism, such as tinnitus, dizziness, and gastrointestinal disturbance. If ringing in the ears, deafness, skin rash, or visual disturbances occur, the drug should be discontinued.

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Product Information as of September, 1977

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8-3305 (Y371A)

# BCG Vaccines

CENTER FOR DISEASE CONTROL
H.E.W., Public Health Service, Atlanta, GA.

### Introduction

Tuberculosis cases and deaths in the United States have declined steadily since reporting began in the 19th century. In 1977 there were approximately 30,000 reported cases and 3,000 deaths, for rates of 13.9 (cases) and 1.4 (deaths) per 100,000 population. These rates are 40% and 60% lower than the corresponding rates for 1967. The rate of infection, judged by the prevalence of positive tuberculin skin tests, has also declined, particularly for susceptible groups, such as young children. The prevalence of positive reactors among children entering school is now estimated to be 0.2%, and among adolescents, 0.7%. The current annual infection rate is estimated to be 0.03%, based on the prevalence among 6-year-olds.

The incidence of tuberculosis cases varies broadly among different segments of the population and in different localities. Cases occur twice as frequently in males as in females. Rates increase sharply with age in both sexes and all races. More than 80% of reported cases are in persons over 25 years of age, most of whom were infected several years previously. Reported cases are generally typical post-primary pulmonary disease. The risk of infection is greatest for those who have repeated exposure to persons with unrecognized or untreated sputum-positive pulmonary tuberculosis. Chemotherapy rapidly reduces the infectivity of cases.

Efforts to control tuberculosis in the United States are directed toward the early identification and treatment of cases and preventive therapy with isoniazid for infected persons at high risk of developing disease. In this country, vaccine prepared from the Bacillus of Calmette and Guérin (BCG) has been used mainly for selected groups of uninfected persons who live or work where they have an unavoidable risk of exposure to tuberculosis.

### BCG Vaccines

BCG was derived from a strain of *Mycobacterium bovis* attenuated through years of serial passage in culture by Calmette and Guérin at the Pasteur Institute, Lille, France. It was first administered to humans in 1921.

There are many BCG vaccines* available in the world today; all are derived from the original strain, but they vary in immunogenicity, efficacy, and reactogenicity. Variation probaby has been the result of genetic changes in the bacterial strains; differences in techniques of production; methods and routes of vaccine administration; and characteristic of the populations and environments in which vaccine has been studied. Controlled trials—all conducted prior to 1955—of liquid vaccines prepared from different BCG strains showed protection ranging from 0 to 80%.

The vaccines now available in the United States differ from products used in the field trials in that additional culture passages have since taken place, and there have been various modifications in methods of preparation and preservation. The efficacy of these current vaccines has not been demonstrated directly and can only be inferred.

Production standards for BCG vaccines (Bureau of Biologics, Food and Drug Administration) specify that they be freeze-dried products containing live bacteria from a documented strain of the Bacillus of Calmette and Guérin. The strain must demonstrate various specified characteristics of safety and potency and be capable of inducing tuberculin sensitivity in guinea pigs and humans. (The assumed relationship between sensitivity and immunity has not been proven.)

Freeze-dried vaccine should be reconstituted, protected from exposure to light, and used within 8 hours.

### Vaccine Usage

#### General Recommendations

Modern methods of case detection, chemotherapy, and preventive treatment can be highly successful in controlling tuberculosis. Nevertheless, an effective BCG vaccine may be useful under certain circumstances. In particular, BCG may benefit uninfected persons with repeated exposure to infective cases who cannot or will not obtain or accept treatment.

#### Recommended Vaccine Recipients

1. BCG vaccination should be seriously considered for individuals, such as infants in a household, who are tuberculin skin-test negative[1] but who have repeated exposure to persistently untreated or in-

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* official name: BCG Vaccine.

effectively treated patients with sputum-positive pulmonary tuberculosis.

2. BCG vaccination should be considered for groups in which an excessive rate of new infections can be demonstrated and the usual surveillance and treatment programs have failed or are not feasible. Such groups might exist among those without a regular source of health care.

Adequate surveillance and control measures should be possible to protect groups such as health workers.[2] However, some health workers may be at increased risk of repeated exposure, especially those working in institutions serving major urban population centers in which the endemic prevalence of tuberculosis is relatively high. BCG vaccine should be considered when the frequency of skin-test conversion representing new infections[3] exceeds 1% annually.

### Schedule

BCG should be reserved for persons who are skin-test negative to 5 TU of tuberculin, PPD. Those who receive BCG should have a tuberculin skin test 2-3 months later. If that skin test is negative and the indications for BCG remain, a second dose of vaccine should be given. Dosage is indicated by the manufacturer in the package labeling; one-half of the usual dose should be given to persons under 28 days old. If the indications for immunization persist, these children should receive a full dose after attaining 1 year of age.

### Administration Technique

The World Health Organization recommends that BCG be given by the intradermal route in order to provide a uniform and reliable dose. In the United States, however, vaccines for intradermal and for percutaneous administration are licensed, and vaccination should be only by the route indicated in the package labeling.

## Risks and Side Effects

BCG vaccine has been associated with adverse reactions including severe or prolonged ulceration at the vaccination site, lymphadenitis, and—very rarely—osteomyelitis, lupoid reactions, disseminated BCG infection, and death. Available data on adverse reactions do not necessarily pertain to the vaccines currently licensed in the United States, and the reported frequency of complications has varied greatly, depending in part on the extent of the surveillance effort. For example, the frequency of ulceration and lymphadenitis has been reported to range from 1% to 10%, depending on the vaccine, the dosage, and the age of vaccinees. Osteomyelitis has been reported to occur in 1 per 1,000,000 vaccinees, although limited information indicates that with newborns it may be higher. Disseminated BCG infection and death are very rare (1-10 per 10,000,000 vaccinees) and occur almost exclusively in children with impaired immune responses.

## Precautions and Contraindications

### Altered Immune States

BCG for prevention of tuberculosis should not be given to persons with impaired immune responses such as occur with congenital immunodeficiency, leukemia, lymphoma, or generalized malignancy, and when immunologic responses have been suppressed with steroids, alkylating agents, antimetabolites, or radiation.

### Pregnancy

Although no harmful effects of BCG on the fetus have been observed, it is prudent to avoid vaccination during pregnancy unless there is an immediate excessive risk of unavoidable exposure to infective tuberculosis.

### Interpretation of Tuberculin Test

After BCG vaccination, it is usually not possible to distinguish between a tuberculin reaction caused by virulent supra-infection and one resulting from persistent postvaccination sensitivity. Therefore, caution is advised in attributing a positive skin test to BCG (except in the immediate postvaccination period), especially if the vaccinee has recently been exposed to infective tuberculosis.

### Tuberculosis in Vaccinated Persons

Since full, lasting protection from BCG vaccination cannot be assured, tuberculosis should be included in the differential diagnosis of any tuberculosis-like illness in a BCG vaccinee.

## Surveillance

All suspected adverse reaction to BCG should be carefully investigated and reported to health authorities. These reactions occasionally occur as long as a year or more after vaccination.

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# Mass Screening for Lung Cancer

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### Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

A conference on screening for lung cancer was held September 18-20, 1978 in Reston, Virginia, under the sponsorship of the Division of Cancer Control and Rehabilitation, National Cancer Institute, in collaboration with the National Institute for Occupational Safety and Health. It was one of a series of meetings held by the Division to reach a consensus on the current prospects for broader application of the results of medical research. The purpose of this conference was to determine whether there were adequate scientific grounds for concluding that mass screening of individuals at high risk of lung cancer (followed by appropriate diagnostic work-up and treatment of those individuals with suspicious findings) would reduce mortality from the disease.

Participants in the conference included chest physicians, surgeons, radiologists, endoscopists, pathologists, cytologists, immunologists, epidemiologists, and statisticians, as well as representatives from occupational and family medical practice, government, industry and labor.

Lung cancer now accounts for about 14% of all cancer cases and 22% of all cancer deaths; incidence in men at present is about four times that in women, but incidence in women is increasing more rapidly than men. Cigarette smoking is the predominant cause in both sexes, but increased risk of lung cancer has been reported also in asbestos workers, coke oven workers, uranium miners, workers in certain metal smelting and refining plants, and in some branches of the chemical industry. In most instances that have been studied, cigarette smoking significantly increased the risk of lung cancer among such workers. Generally, incidence has been found to be proportional to the dose or duration of exposure to the carcinogen. Variations in individual susceptibility, possibly due to genetic effects, immune factors, or other respiratory diseases, appear to play a role in lung cancer risk.

The pathogenesis of lung cancer has been deduced from histological studies of bronchial tissue from patients dying of lung cancer, and from smokers, ex-smokers, non-smokers, and those without pulmonary disease who have died from other causes. Progressively increasing frequency of hyperplasia and of atypical cells has been found in the bronchial epithelium in proportion to the duration and amount of cigarette smoking. Although the frequency of these abnormal changes has been greatest near the bifurcation of the major bronchi, they also have been found throughout

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Copies of booklet "NIH Consensus Development Conferences Summaries from 1977-78," may be obtained from the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205. Copies of 1979 individual conferences are also available.

the tracheobronchial tree. All stages, from slight hyperplasia to carincoma-in-situ and invasive cancer, have been observed. The bronchial epithelium of ex-smokers has shown histological evidence of reversibility of premalignant lesions after cessation of smoking. However, a basis for correlating the abnormalities of cells shed into the sputum with the various premalignant lesions that have been detected histologically has not been clearly established.

In discussing the requirements for satisfactory screening tests, care was taken to distinguish between screening and diagnosis. It was recognized that the purpose of screening is to sort out rapidly and effectively those asymptomatic members of a population who probably have the disease in question from those who do not, leaving final determinations to be made by appropriate diagnostic methods.

Among the potentially useful methods for detecting pre-symptomatic lung cancer, only chest X-ray and cytological examination of the sputum have been found to be sufficiently well developed at present to warrant consideration for practical application in screening. Strict control of standards and of technical competence is necessary in both cases to ensure reliability. The two tests appear to be complementary in that peripheral tumors are detected more readily by radiography while sputum cytology is more effective in detecting lesions in the larger bronchi.

Interim results of controlled clinical trials that involve screening for lung cancer by chest radiography and sputum cytology were reviewed. These trials, now in progress, include a total of about 15,000 heavy smokers over the age of 45 judged to be at high risk of developing lung cancer, and a similar number of controls. The results will be analyzed to determine the effect of screening (with subsequent diagnosis and treatment of disease discovered during the screening) on lung cancer mortality, but the data accumulated do not yet show any significant difference in mortality between the screened and the control groups. It is believed that any difference in mortality which might be achieved as a result of screening should be detectable in another two to three years.

Other studies of the effects on lung cancer mortality due to screening by chest radiography or sputum cytology, or both, also showed negative or equivocal results.

The following conclusions express the findings of the conference:

1. Current prospective studies of asymptomatic individuals who have been screened for lung cancer by chest X-ray examination and sputum cytology do not at presend show any evidence of a significant reduction in mortality from the disease. These studies must be continued for several more years before the accumulated information will be sufficient to allow a relationship between screening and mortality to be determined. Results of these studies should be kept under continuing review.
2. Until the value of screening for lung cancer by these methods has been demonstrated, mass screening programs should be limited to well-designed, controlled studies, with provision for analysis of results, and for further diagnostic work-up and treatment, when indicated.
3. While some screening programs for lung cancer have been initiated among workers in certain industries, caution is strongly recommended in starting any new ones. Screened workers cannot be assured of an overall benefit on the basis of existing data.
4. None of the above recommendations on the application of chest radiography and sputum cytology in *screening* is intended to apply to their *diagnostic* use in individuals who present to physicians with signs or symptoms that suggest lung cancer.
5. Continued research on better methods of screening for lung cancer, including improvements in the methods now under trial, should be strongly supported. At present, no other techniques appear to be ready for clinical application.
6. Whether for screening or diagnosis, the control of quality in performing and interpreting chest radiography and sputum cytology is essential. (Radiographic quality can be assured through supervision by qualified radiologists. Accuracy of interpretation in screening can be enhanced through double reading of chest X-rays by appropriately trained individuals. Qualifications of cytopathologists should likewise be assured through such measures as competency examinations and continuing education programs. Standards of performance of cytopathological laboratories should be determined by an appropriate accrediting body.)
7. Since screening by current methods is unlikely to solve the problem of lung cancer control, strenuous efforts should be devoted to primary prevention. The greatest reduction in mortality can be achieved by cessation of cigarette smoking, with additional important benefits from reduction of exposure to other respiratory carcinogens (enviornmental and occupational). Elimination of combined exposure to cigarette smoke and other airborne carcinogens is particularly important because their effects on lung cancer incidence are often synergistic.

# Women Physicians in Organized Medicine

*The following is a report of the AMA Council on Long Range Planning and Development to the House of Delegates at its Annual Meeting in July, 1979.*

The Board of Trustees asked that the Council respond to the charge from the House of Delegates to "... develop plans of action to increase participation of women physicians in the activities of organized medicine" (Substitute Resolution 5, I-77). The Council reviewed a substantial amount of data and information on the overall subject of women physicians' role in medicine and spent a half day discussing the subject with Dr. Charlotte Kerr, President of the American Medical Women's Association, and Dr. Ann Barlow, a member of the AMWA Board. This report provides a brief profile of the population of women physicians in the U.S. and makes some recommendations on what AMA can do to encourage more participation by women physicians.

The Profile on Medical Practice, 1978, includes the following statistical information on the population of women physicians in the U.S.:

> On December 31, 1976, there were 38,761 women physicians in the United States and possessions. This represents 9.7% of the total physician population. Seventy-four point seven percent (28,966) of the women physicians were active and classified, with known addresses. The distribution by activity was:
>
> patient care—25,896 (89%)
> medical teaching—844 (3%)
> administration—1,077 (4%)
> research—816 (3%)
> other—333 (1%)
>
> The specialty group distribution of active, classified women physicians with known addresses was:
>
> general practice—3,164 (11%)
> medical specialty—10,884 (38%)
> surgical specialty—3,362 (12%)
> other specialty—11,556 (40%)
>
> On December 31, 1976, the mean age of male physicians was 46.3 years while the mean age of women physicians was 42.4 years. Note that:
>
> Thirty-nine point three percent of the women physicians were less than 35 years of age, while 26.7% were less than 35.
>
> Nine point eight percent of women physicians were 65 and older, while 13.4% of the male physicians were 65 and older.

The number of women entering medicine has increased rapidly over the past 20 years. The table indicates that in 1959-60 women represented 6.9% of applicants to medical schools, 6.0% of the entering class, and 5.7% of the graduates. These figures for the 1976-77 academic year were 24.3% of applicants to medical schools, 24.7% of the entering class, and 19.2% of the graduates. It has been estimated that by the early 1980s, one-third of the medical school graduates will be women.

An article titled "A Profile of the Woman Physician" (JAMA, November 1977) provides some interesting data on the characteristics of the "average" woman physician. These data are from a survey conducted among a sample of women physicians in the Detroit metropolitan area, and therefore may have some statistical bias toward characteristics of women physicians in urban areas:

> The typical woman physician is 46 years old, Caucasian and Protestant; is a member of the upper middle class; is married, most likely to a physician, and has 2.5 children. Forty-seven percent were reared in an urban environment.
>
> The typical woman physician has worked continuously since graduation from medical school and is presently working full-time. She is board certified and her main task is patient care in one of the primary care specialties. She works in a private office and is self-employed with median earnings of $36,000 per year.
>
> Fifty-seven percent of the working women physicians worked in a private office, while an additional 29% worked in a hospital or clinic. Over one-third were self-employed and worked

alone, 20% worked with a partner and 14% were in a group. Most women who worked for someone else were employed by a hospital. Women physicians tend to practice in salaried positions to a greater extent than male physicians.

Almost three-fourths of the survey respondents reported patient care as their major activity, defined as constituting at least one-third of their time, followed by teaching, research and administration, in that order. Eleven percent of the women reported teaching as their major activity.

As the range of hours per week differed among the women, several analyses were undertaken concerning the impact of marriage and children on full-time versus part-time practice. The most frequent method of dealing with the problems in these areas was to arrange for someone to care for their children, followed by fewer working hours, or a temporary withdrawal from professional activities.

It is apparent that the unwillingness of many respondents to make a choice between family and career has resulted in role strains in varying degrees. This strain was reflected in the expressed need for supportive services; not unexpectedly among the women with young children, child care arrangements were the major concern.

### Women Physicians' Participation in Medical Organizations

In the United States there are approximately 40,000 women physicians, of whom 7,000 (18%) are members of the AMA. Data is not available on the number of women physicians who are members of county and state societies, but not members of the AMA.

The AMA's Department of Membership Development conducted a mail survey of state and specialty societies and found the following:

1. Within 40 states that responded to the survey, there were 51 elected state positions and 191 appointed state positions held by women physicians, for a total of 242 positions at state level.
2. Within the same 40 states there are 114 county-level elected positions held by women physicians and 71 appointed positions at the county, for a total of 185.
3. Within the 17 specialty societies that responded to the survey there are 15 elected positions held by women physicians and 127 appointed positions, for a total of 142.
4. Within the 57 total responding organizations there are 569 elected or appointed positions held by women physicians.

While these figures may seem encouraging, women physicians still represent a disproportionately low minority among medical society participants and office holders. "A Profile of the Woman Physician" indicated that most of the respondents belonged to professional organizations, but only 30% were considered active members, i.e., attended meetings six or more times a year.

### Discussion and Recommendations

During the Council's meeting with the representatives of the AMWA, some of the reasons for relatively low participation by women physicians were discussed. Among the reasons mentioned is the fact that much of the process for filling appointed positions is informal and there is relatively little opportunity for women physicians to become involved. Another problem is the woman physician's feeling of exclusion at county society meetings, causing women to turn to the AMWA for peer group professional exchange. However, the AMWA representatives indicated that the AMWA has a file of over 600 women physicians, 46% of whom are AMA

Table

WOMEN IN U.S. MEDICAL SCHOOLS, SELECTED YEARS 1949-1976

| | *Women Applicants* | | *Women in Entering Class* | | *Total Women Enrolled* | | *Women Graduates* | |
|---|---|---|---|---|---|---|---|---|
| *Academic Year* | *Number* | *Percent of Total* | *Number* | *Percent of Total* | *Number* | *Percent of Total* | *Number* | *Percent of Total* |
| 1949-50 | 1,390 | 5.7 | 387 | 5.5 | 1,806 | 7.2 | 595 | 10.7 |
| 1959-60 | 1,026 | 6.9 | 494 | 6.0 | 1,710 | 5.7 | 405 | 5.7 |
| 1964-65 | 1,731 | 9.0 | 786 | 8.9 | 2,503 | 7.7 | 503 | 6.8 |
| 1969-70 | 2,289 | 9.4 | 952 | 9.2 | 3,390 | 9.0 | 700 | 8.4 |
| 1970-71 | 2,734 | 10.9 | 1,256 | 11.1 | 3,894 | 9.6 | 827 | 9.2 |
| 1971-72 | 3,737 | 12.8 | 1,693 | 13.7 | 4,755 | 10.9 | 860 | 9.0 |
| 1972-73 | 5,480 | 15.2 | 2,315 | 16.9 | 6,090 | 12.8 | 924 | 8.9 |
| 1973-74 | 7,202 | 17.8 | 2,743 | 19.6 | 7,731[a] | 15.4[a] | 1,264 | 11.1 |
| 1974-75 | 8,712 | 20.4 | 3,260 | 22.3 | 9,786 | 18.1 | 1,706 | 13.4 |
| 1975-76 | 9,575 | 22.6 | 3,656 | 23.8 | 11,527 | 20.5 | 2,200 | 16.2 |
| 1976-77 | 10,244 | 24.3 | 3,876 | 24.7 | 13,059 | 22.4 | 2,611 | 19.2 |

[a] Harvard did not provide enrollment figures.

Source: Medical Education in the United States 1976-1977, *JAMA* 238:2771, December 26, 1977.

members, who would be qualified and have expressed an interest in serving the AMA.

The Council discussed at some length the question of slotted positions for women physicians on AMA councils and quota systems for assuring adequate representation of women physicians. It was generally agreed that neither of these mechanisms is desirable.

The problem of how the AMA can bring about more participation by women physicians is a difficult one to deal with because participation in the AMA, especially in any official capacity, is almost entirely through the federation structure. The AMA cannot mandate action on the part of state and county societies and must rely on persuasion campaigns. The Council believes that eventually there will be more participation by women physicians simply by virtue of their increasing numbers, but in the short term there are some actions that the AMA can take to increase participation.

The Council recommends the following actions be taken:

1. The AMA should undertake a special membership effort aimed at encouraging women physicians to join organized medicine at all levels. This campaign should promote AMA membership benefits and AMA activities that respond to the particular need of women physicians.
2. The AMA and the AMWA should engage in a coordinated effort to encourage membership and participation in both organizations.
3. The AMA, through AM News and its other publications, should attempt to dispell the stereotypes and misconceptions about women physicians and should publicize women physicians' contributions to medicine across a wide variety of professional activities in order to establish a more realistic "role model" for women physicians.
4. Encourage state, county and specialty societies to make special efforts to recruit women physicians to membership in organized medicine.
5. Encourage state, county and specialty societies to appoint and nominate women physicians to committees, officerships, delegates seats, etc., and to do this with the attitude of recognizing and tapping their professional capabilities rather than simply of having a "proportionate" number of women physician participants.

The above recommendations are all of the type that should be implemented with vitality. The Council believes that if the recommendations are backed by solid effort for a few years momentum will be generated rather quickly. The benefit to the AMA and all levels of organized medicine will be substantial and permanent.

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## Priorities for Medicare

Congress has established the National Center for Health Care Technology to help determine which of the bewildering array of medical equipment and techniques should be paid for by Medicare, according to an article in the *National Journal.*

The new Center has had to operate with only $175,000—not even enough to set up shop. But it has already begun to consider whether Medicare should pay the bills when the elderly receive such new services as electromagnetic treatment of fractures and electric pain-relieving techniques.

Likely to be reviewed are popular, billion-dollar-a-year procedures such as coronary artery bypass and kidney dialysis as well as small but commonly used equipment and techniques that can also run up large bills.

On the other hand, there are some technologies where Seymour Perry, Acting Director of the Center, says the Center favors "wider applications." Amniocentesis "is not being used widely enough for example," Perry believes. "There were 150,000 abnormal births last year but only 15,000 amniocenteses. We can't tell what the saving will be to the family and society with wider use of this procedure to avoid abnormal births."

# NEW MEMBERS

## HARTFORD COUNTY

**Shahram Ayazi, M.D.**, Farmington
**George Bacall, M.D.**, Hartford
**Edward H. Benjamin, M.D.**, Enfield
**Edward A. Blanchette, M.D.**, Newington
**Carl D. Bomar, M.D.**, Bristol
**James C. Boyle, M.D.**, Hartford
**J. Leonard Brandt, M.D.**, Hartford
**Spencer L. Butterfield, M.D.**, Hartford
**Soo-Kang Choi, M.D.**, Manchester
**Gary P. Cohen, M.D.**, Simsbury
**Lauren A. Daman, M.D.**, Hartford
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**David J. Phillips, M.D.**, Hartford
**Jorgelina G. Ramonet, M.D.**, Hartford
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"Possibly" effective: as adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

Final classification of the less-than-effective indications requires further investigation.

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# Status Report on Professional Standards Review Organizations

*The following is a report prepared by the Council on Medical Service of the AMA and accepted by the AMA House of Delegates at its Annual Meeting in July, 1979.*

The Council on Medical Service and its Ad Hoc Committee on PSRO have continued to monitor the Professional Standards Review Organizations program, and present the following status report.

### PSRO Program Status

As of April 1979, the Department of Health, Edcuation and Welfare (DHEW) had approved contracts for 188 conditional PSROs and three planning PSROs out of a total of 195 designated PSRO areas; thus, four areas remain without PSRO activity. Nebraska is without a local, physician-sponsored PSRO, and DHEW is initiating the process of soliciting an "alternate" PSRO for the state. Two PSROs failed to receive contract renewals: the Tennessee Area II PSRO (Nashville) because of allegations by DHEW of mismanagement; and the Indiana Area I PSRO (Calumet) because of allegedly delayed and inappropriate implementation of review. Finally, the California Area XIX PSRO (Long Beach) had refused to renew its contract with DHEW because the PSRO board considered the proposed federal funding level insufficient for PSRO operations. Reportedly, DHEW officials are interested in consolidating California's Area XIX with other area PSROs.

### PSRO Program Funding

PSROs throughout the country, and the Office of Professional Standards Review Organization (OPSRO) within DHEW, are being forced to adapt to an environment of fiscal austerity. The FY 1979 PSRO budget of $150 million ($85 million from the Medicare Trust Fund and $65 million from direct appropriations) has in effect required PSROs to reduce their review costs by approximately thirty percent, down to an average of $8.70 per view.

Congressional hearings on DHEW's $152.6 million FY 1980 budget request appear to be focusing on PSRO performance and cost reduction efforts. In response to Congressional pressure to cut program costs, OPSRO officials are stressing: elimination of nonperforming PSROs; focused review (on less than 100% of admission); possible voluntary mergers of small PSROs; and PSRO "management by objective".

In addition, PSROs and OPSRO are attempting to identify mechanisms for controlling hospital review costs. Funds for concurrent and retrospective review of hospital care come from the Medicare Trust Fund portion of the PSRO program budget. In the case of delegated review (approximately 70% of hospital review is delegated), the Medicare fiscal intermediary reimburses the hospital directly for costs incurred in conducting PSRO review.

For the first time in PSRO program history, Congress limited the Medicare Trust Funds available for PSRO hospital review. DHEW's Office of PSRO will now have the additional responsibility of monitoring Trust Fund expenditures to assure that the $85 million limit is not exceeded, a particularly difficult task in delegated hospitals where PSROs currently have little direct control over expenditures. Limits on the Trust Fund expenditures have renewed interest in non-delegated PSRO hospital review and accordingly, in some hospitals PSROs have withdrawn delegation status.

Other effects of PSRO budgetary constraints include limited funding of PSRO long-term care review (only about 54 PSROs will be funded for such review), and limited ambulatory care review.

### PSRO Regulations and Program Policy

During the last six months DHEW completed "proposed" and "final" versions of several PSRO-related rules and transmittals which are detailed below:

1. **PSRO Sanctions**

   Expected to be published as final rules in the near future are proposed sanction regulations which establish procedures under which the Secretary of HEW could sanction a practitioner or provider who furnishes or orders items or services in violation of obligations found in the PSRO law relating to the necessity and quality of health care services.

   The American Medical Association responded to these proposed sanction regulations in December 1978, expressing concern with their failure to provide for a full, fair and impartial evidentiary hearing prior to imposition and public disclosure of a sanction. The AMA also expressed concern that the proposed sanction rules may fail to protect patient, provider, and practitioner confidentiality prior to making the official determination of a violation and sanction.

2. **Confidentiality and Disclosure of Professional Standards Review Organization Information**

   On January 15, 1979, DHEW published proposed rules governing the "Confidentiality and Disclosure of Professional Standards Review Organizations Information." The law now provides that PSRO information may be disclosed under four conditions: (1) to the extent necessary to carry out PSRO functions; (2) to certain agencies investigating fraud and abuse; (3) to health planning agencies (without individual identifiers); and (4) as defined in regulation.

   The regulations proposed in January divide PSRO information into "non-confidential" and "confidential" data, and restrict disclosure of the latter (which includes individual identifying information, PSRO deliberations and sanction reports). Individual health facilities, however, may be identified.

   The Association questioned the lack of a requirement for patient consent in a provision of the regulations which would allow institutions or practitioners the right to grant PSROs access to non-federal patient records.

   AMA comments also stressed the need for protection against redisclosure, protection of the patient against inappropriate disclosure to a patient's family, guardian, or proxy, and for application of appropriate review procedures and safeguards prior to release of PSRO information for research purposes.

3. **Other PSRO Program Regulations and Transmittals**

   Proposed regulations published on March 5, 1979, describe the process for reconsiderations, hearings and appeals of PSRO medical necessity and level-of-care determinations. Four ascending levels of review are provided: (1) reconsideration by the local PSRO; (2) statewide Professional Standards Review Council consideration of a PSRO decision (if a statewide council exists); (3) appeal to the Social Security Administration's Bureau of Hearings and Appeals (BHA); and (4) judicial review.

   The regulations, however, allow access to the BHA and judicial appeal levels only to patients; practitioners and providers may only appeal to the PSRO and the statewide council. An AMA amendment to the PSRO law, to be introduced into Congress this year, would open all levels of the reconsideration process to a provider or practitioner.

   Final Medicare and Medicaid Regulations on "Conformance with Professional Standards Review Regulations on Review, Certification, and Payment Activities" were published on March 19, 1979. These regulations eliminate certain duplicative Medicare and Medicaid utilization review, assistance requirements where a PSRO has assumed binding review responsibility. These regulations also provide for conformance of Medicare and Medicaid regulations with PSRO denial, payment, and hearing procedures where the PSRO has assumed review authority.

   On March 16, 1979, DHEW published proposed regulations on PSRO review authority of intermediate care facilities (ICFs). These regulations describe conditions under which the Secretary may find a state Medicaid agency's utilization control, utilization review, and quality assurance systems in ICFs to be "ineffective," and thereby transfer this review responsibility to the PSRO. At the present time, under most circumstances, PSROs are specifically authorized to conduct long-term care review only in skilled nursing facilities (SNFs). The March 16 regulations also describe criteria for determining when review by both the PSRO and Medicaid agency in multilevel facilities (SNF and ICF) is "inefficient" and should be conducted by the PSRO alone.

   Finally, in an effort to provide PSROs with greater management flexibility, program transmittals issued by DHEW now lift the limit of $0.75 per discharge for data processing costs and also allow PSROs to subcontract some of their functions.

### PSRO Data Collection and Management

As reported to this House in Council on Medical Service Report G (I-78) "PSRO Data Collection and Management", plans for collecting the Uniform Hospital Discharge Data Set (UHDDS) through fiscal intermediaries and agents rather than through PSROs are continuing in the Department of Health, Education and Welfare.*

In May 1978, the Under Secretary of DHEW indicated a "tentative preference" for transferring this collection responsibility. In August, a strategy for implementation of the tentative decision was outlined despite considerable opposition from PSROs.

At the time of the writing of this report, DHEW was preparing a Notice for Proposed Rulemaking, which would indentify criteria for selection of statewide or regional collectors and processors of the UHDDS. According to DHEW officials, fiscal intermediaries, PSROs, State Cooperative Health Statistics Systems, State Health Agencies, and medical records abstracting firms would be among those eligible to bid competitively for the UHDDS collecting and processing function. The designated central UHDDS collector would be responsible for providing appropriate health related organizations and agencies (PSROs, HSAs, etc.) with UHDDS information. However, according to Health Standards and Quality Bureau staff, few PSROs are likely to be able to meet the criteria and are, therefore, not expected to be selected as the collectors and processors.

At the 1978 Interim Session, the House of Delegates approved a Council on Medical Service recommendation that the Association strongly oppose collection of any UHDDS data by fiscal intermediaries rather than PSROs; this policy has been forcefully relayed to DHEW on several occasions. The Association has requested DHEW to "reconsider these proposed changes and, instead, continue to upgrade and refine existing, high quality PSRO data systems."

In addition to the question of who will collect the UHDDS, the issue of the inclusion of patient and physician identifiers remains unresolved. DHEW has raised again the need for a common identifier for physicians and patients. Also at the 1978 Interim Meeting, the House of Delegates in adopting Council on Medical Service Report G stated that ". . . AMA should continue to negotiate with DHEW to assure that PSROs have a continuing role in the control over confidential data containing individual patient and physician identifiers, and that such identifiers not be required in any uniform system of reporting hospital discharge data."

Also unanswered is the question of whether DHEW will pursue a long-range plan for collection of similar data on non-federal beneficiaries. Substitute Resolution 122 (I-78), adopted by the House of Delegates, opposes collection of the UHDDS on "any patient whose care is not paid for under federal programs . . ." In adopting Substitute Resolution 122, the House referred a related statement through the Board of Trustees to the Council on Medical Service for further study. The referred statement recommends:

> "That AMA express strong opposition to federal attempts to collect, both regionally and nationally, data containing either the Uniform Discharge Data Set or the hospital billing data. Collection and use of these data must remain a local responsibility. AMA disapproval extends to both patients paid for by government programs, and more particularly, private patients."

The Council believes that the AMA should continue to oppose federal collection of the UHDDS or billing data on private patients. The Council recognizes, however, that the federal government has the authority by law to provide for collection of such data on patients paid for by federal programs, and believes that such authority is appropriate to ensuring responsible expenditure of public funds. As noted previously, the Council believes that local PSROs, and not fiscal intermediaries, should be the mechanism through which such data is collected.

Based on the foregoing, the Council on Medical Service *recommends* that Substitute Resolution 122 (I-78) be reaffirmed in lieu of the referred statement.

### Sample Criteria Development Projects

The American Medical Association, through a contract with the Department of Health, Education, and Welfare, is coordinating development of sample surgical and diagnostic screening criteria sets covering approximately 75 percent of the procedures in each major surgical specialty area. These criteria will be made available to PSROs for their possible adaptation and use in reviewing surgical and diagnostic procedures.

In March 1979, 141 draft criteria sets were transmitted to DHEW with draft introductory and instructional materials. At the time this report was written, the sample criteria sets were being tested on-site at seven PSROs and had been distributed for comment to other PSROs, national medical specialty societies, state medical associations, and metropolitan country medical societies. Based on the evaluation results and comments received, the criteria and accompanying materials will be appropriately revised prior to final transmission to DHEW in September 1979.

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*The UHDDS is part of the required standard data set collected by the PSROs. This data set includes, for example: patient identification; admission and discharge dates; attending and operating physician identification; diagnoses; etc. Presently, PSROs report this data to DHEW on a quarterly basis, omitting the patient and practitioner identifiers.

Through an earlier DHEW contract, the American Medical Association developed "Sample Criteria for Short Stay Hospital Review" in 1976. These model criteria for medical diagnoses are currently used, or have been adapted, by many PSROs and peer review committees in screening and reviewing the quality and appropriateness of hospital care. The American Association of Professional Standards Review Organizations, through a contract with DHEW, is now completing an update of these short-stay hospital criteria and accompanying instructional materials. The National Professional Standards Review Council, which is responsible for disseminating sets of "reference criteria" to PSROs throughout the country, will review the updated short-stay hospital criteria.

### AMA Proposed Amendments to the PSRO Law

Eighteen amendments to the PSRO provisions of the Social Security Act have been drafted for submission to the 96th Congress; a summary of the proposed amendments is attached to this report as an Appendix.

In addition to the proposed amendments, the AMA has drafted legislation which would make PSRO data exempt from disclosure under the Freedom of Information Act (FOIA). This legislation responds to a case still pending in the U.S. District Court in Washington, D.C., in which it was ruled that the District of Columbia PSRO is an agent of the federal government for purposes of disclosure under the Freedom of Information Act. The Court still has not ruled on the applicability of specific exemptions under FOIA to individually catalogued items of PSRO information. Senator Robert Schweiker (R-Penn.) has also reintroduced legislation into the 96th Congress which would prohibit release of PSRO information through the Freedom of Information Act.

### National Professional Standards Review Council

At the January 1979, meeting of the National Professional Standards Review Council, Helen Constance Bonbrest, M.D., was sworn in as a Council member. An internist, Doctor Bonbest is currently Associate Director for Health Services Program at the University of Illinois, and is the third new addition to the eleven member Council since September 1978. Current Council members include John W. Bussman, M.D., Chairman, Wyndham B. Blanton, M.D., Robert S. Hare, M.D., Robert T. Kelly, M.D., William Fred Lucas, M.D., Kenneth A. Platt, M.D., Raymond J. Saloom, D.O., Edyth H. Schoenrich, M.D., and Alonzo S. Yerby, M.D. The terms of Doctors Blanton, Hare, Kelly, Lucas, and Saloom expire in July 1979.

The Council on Medical Service and its Ad Hoc Committee on PSRO will continue to closely monitor the Professional Standards Review Organizations program in an effort to see that it continues as a professionally directed effort to ensure the quality and appropriateness of care provided to patients.

### PSRO AMENDMENTS

The following represents the substance of the AMA developed amendments to the PSRO law:

*1 - Section 1152 (b) (1)*

The definition of "qualified organization" under this Section should be expanded so that organizations, including foundations, designated by medical societies will be specifically eligible for consideration as a PSRO.

*2 - Section 1156 and Section 1155 (a)*

A. Section 1156 should be amended to direct specifically the respective PSROs to ascertain and develop appropriate guidelines (referring to norms, criteria, and standards) drawing upon the expertise of national, state and county medical associations and specialty societies.

B. The law should be amended to state specifically that such guidelines (referring to norms, criteria and standards) are to be guides only and cannot be substituted for individual professional judgment.

C. Section 1155 (a) should also clearly include the role of the local PSRO in defining areas pertaining to necessity, quality or appropriateness.

*3 - Sections 1155 (a) (2), (3); (b) (2)*

Consistent with policy in opposition to preadmission certification of institutional care, such authority presently existing in the PSRO law should be deleted.

*4 - Section 1152 (f)*

An opportunity for physician "polling" on any designation agreement or renewal of an agreement between the Secretary and a PSRO should be afforded when specific percentages of physicians in an area desire a poll.

*5 - Section 1160 (b) (3)*

This section, providing for financial penalties in lieu of termination or suspension, should be repealed. A system of graduated sanctions should be established.

*6 - Sections 1157 and 1160 (b) (1)*

Certain reporting provisions require PSROs to submit to the Statewide Council, for forwarding to the Secretary, all determinations made by the PSRO that a practitioner or a provider has violated any obligation relating to necessity, quality or situs of care furnished. The provisions should be amended to require the PSRO to report to the Statewide Council only when it determines that a pattern of practice requires such attention or that a provider or practitioner has grossly and flagrantly violated the obligations imposed under the Act. Such determinations should be made only after a conference with the provider or practitioner in an attempt to seek compliance, and a finding that he or it has shown an inability or lack of desire or intention to comply with the program requirements. In addition, the provisions should be amended to provide to the practitioner or provider a full, fair and impartial evidentiary hearing prior to the imposition of a sanction and public disclosure thereof.

*7 - Section 1166*

This Section should be amended to provide that the (a) written records (rather than just "patient records" currently exempted from subpoena or discovery proceedings under PSRO law) of PSROs, Statewide Professional Standards Review Councils, and the National Professional Standards Review Council, (b) the identity of any member, employee, or person providing information, counsel or services, or (c) the discussion or deliberations of any such organization, council member, employee, or person shall not be subject to subpoena or discovery proceedings.

*8 - Section 1167 (c)*

This section should be repealed. That provision purports to limit the liability of an individual furnishing items or services when such individual has acted in compliance with the norms or care applied by a PSRO, provided that he exercised due care in his conduct. This provision could have the unintended and undesirable effect of pressuring practitioners to adhere to the norms.

*9 - Section 1156*

This section of the law should be amended to state the limited functions of the "norms, criteria and standards" developed thereunder and to define their applicability in civil cases.

*10 - Section 1159 (b)*

This section should be amended to allow a provider or practitioner the right of administrative hearing and judicial review on adverse determinations pertaining to reimbursement.

*11 - Sections 1151, 1155, and 1160*

The law should be amended to provide for PSRO review of care delivered through all federal medical programs such as the Veterans Administration and Public Health Service.

*12 - Section 1155 (b) (4)*

This section should be repealed and replaced with language which would allow PSROs only access to institutional health care facilities for which they have been authorized by law to review as set forth in the PSROs approved review plan.

*13 - Section 1155 (b) (3)*

This section should be repealed. Practitioners and providers are obligated to maintain supporting documentation substantiating the necessity and quality of care provided under Medicare and Medicaid. These recordkeeping requirements are duplicated by an ambiguous authorization under Section 1155 (b) (3) allowing PSROs to "examine the pertinent records" of practitioners and providers. This authority is, at best, redundant and could be the subject of abuse. Unrestrained examinations of medical records would jeopardize physician/patient confidentiality.

*14 - Section 213 of PL 92-603*

This section, which describes circumstances under which payment may be made under Medicare for certain otherwise noncovered items and services, and under which recovery can be made from providers and practitioners, should be repealed.

*15 - Section 207 of PL 92-603*

Provisions relating to utilization review procedures under Medicaid should be repealed.

*16 - Section 1171 (d) (3)*

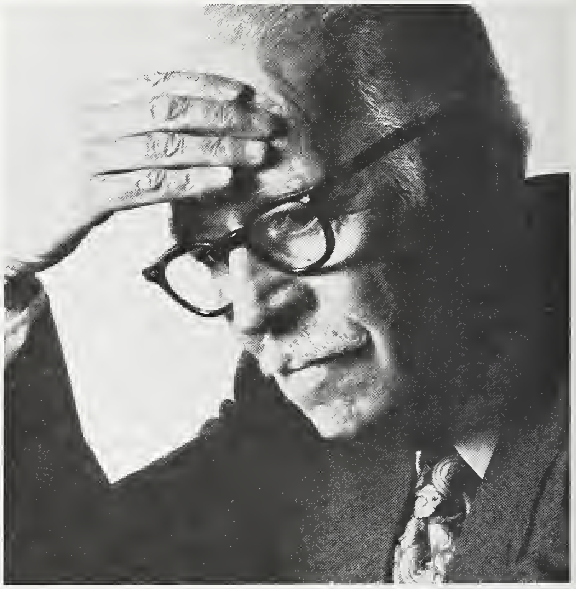
This section should be repealed. It allows the states, at their option, to monitor PSRO review and authorizes the HEW Secretary to suspend the conclusiveness of PSRO Medicaid review and even Medicare review, if it is shown that PSRO review determinations have had an unreasonable and detrimental impact on total state expenditures under Medicaid as well as on the appropriateness of care received by Medicaid beneficiaries. Prior law did not contain a similar provision granting such authority to the states and the HEW Secretary.

*17 - Section 1155 (g)*

This section should be amended to merely authorize a PSRO *at its own request* to conduct ambulatory care review. Prior law contains such a provision but with the passage of PL 95-142, Section 1155 has *required* a fully designated PSRO to undertake ambulatory care review within two years of its becoming fully designated.

*18 - Section 1166 (b)*

This section requires a PSRO to provide data and information to federal and state agencies found by the Secretary as having responsibility for identifying and investigating fraud and abuse. While having the discretion of determining what information should be released to a responsible investigatory agency, the PSRO would still be required to disclose aggregate statistical data to federal and state health planning agencies. Due to concerns over the confidentiality of patient and PSRO records, as well as the potential of diverting the PSRO from its mission of quality assurance, this section of the PSRO law should be repealed.



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1. Shane, S.J.: Canadian Family Physician, November 1973. 2. Lemberg, L.: Practical Cardiology, February 1976.

# Stanford Medical School Suffers Fiscal Ideological Crises

## RICHARD A. KNOX

*Palo Alto, California.* When General Eisenhower was president of Columbia University, the story is told, he once offered to swap jobs with President Harold Willis Dodds of Princeton. Dodds asked why. "Because you don't have a medical school," the general allegedly sighed.

President Richard W. Lyman of Stanford might be forgiven if he feels like Ike these days. Stanford's prestigious medical school and its 668-bed teaching hospital, which together account for 42 percent of the entire university's $380-million operating budget, are in the throes of a fiscal and administrative crisis that offers no ready or painless resolution and shows every prospect of worsening. Last month the situation moved Lyman to ask for the resignation of his dean and vice president for medical affairs, Clayton Rich, who has held the jobs since 1972.

Stanford's current problems are indeed extreme; nonetheless they are representative of issues that face major medical centers nationwide.

Stanford's plight is not only financial; it is inevitably ideological as well, involving as it does who cuts and serves the pieces of a shrinking pie. It concerns the viability of a private institution with a frankly elitist vision of itself. As a recent Stanford manifesto proclaims, the school is devoted far more to biomedical research and the training of the next generations of medical "innovators and pioneers" than to turning out nonacademic physicians, caring for patients, or studying the role of medicine in society. One high-level Stanford administrator said in an interview with *Science*: "I think you would get an argument around here that doctors are even the principal product of Stanford Medical School."

The lines between those who consider general medical training paramount and those who think basic and clinical research of greatest importance at Stanford are drawn. As yet it is not clear what kind of accommodation can be reached. Kenneth Melmon, who was recently lured to Stanford from the University of California at San Francisco, is concerned about what he sees as diminishing public enthusiasm for basic research. He accepted the chairmanship of medicine at Stanford because of the school's reputed commitment to basic research as the underpinning of medical progress. "I really felt this was the place that would outlive the pressure to downplay research and do it royally," he told *Science*. "I still do, but I'm goddamned worried."

Nineteen seventy-eight has been a watershed year for Stanford University Medical Center, a time of gloomy portents from within and thunderbolts from without. "The fiscal problem was on the horizon last fall," said Deputy Dean Lawrence G. Crowley, who will become acting dean 1 January, "but the speed and magnitude of it took us by surprise." Last spring, medical center finance officers concluded that the medical school faced mounting deficits in the years ahead; unless drastic steps were taken, they said, the cumulative shortfall would reach more than $7 million by 1982 to 1983. A key reason lay in the amount of income generated by the school's clinical faculty—the ones who care for patients as opposed to those who only do basic research. In a memo dated 8 June, Dean Rich told the clinical chiefs that soaring expenses had far outstripped the hospital's net revenue, which rose only 2 percent over the previous year; outlays for the clinicians' salaries, for instance, jumped 23 percent this year.

"There has been a reduction in the number of patients seen this year and little price increase, but continued escalation of costs," the dean wrote. "There appears to have been a reduction nationally in the number of office visits and hospital admissions. Locally we see the effects of increasing competition from well-trained private practitioners, and may suffer from reduced referrals as HMO's [health maintenance organizations] are organized in this region, and because of increasingly tight price control and regulations."

Into this perilous situation charged two troublemakers with their view of reform. Eugene Dong, a renegade faculty heart surgeon, and Robert L. Weinmann, an ultraconservative Stanford-trained community neurologist, have been attacking the very basis of Stanford's faculty billing system, a regime that Crowley, who's in charge of it, acknowledges is "a little bizarre." Like perhaps half of all U.S. medical schools, Stanford's full-time clinical faculty are on

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salary in a medical universe that operates according to the time-honored laws of fee-for-service. That is, Stanford clinicians turn over all their fees to the institution, which allocates salaries and applies the rest for activities such as unfunded research and teaching. Under this system, cross-subsidizations within the medical center have become so intricate over the past decade that it seems doubtful that even the administration fully understands who is being paid how much for doing precisely what.

Dong and Weinmann have persisted all year long in raising awkward public questions about the way Stanford bills Medicare and Medi-Cal for patient care: where the money goes, who controls it, how faculty members really spend their government-reimbursed time. Most crucially, they have dredged up the charge that makes all medical educators squirm: double-billing. The charge commonly arises out of the difficulty of sorting out which functions are supposed to be paid for through the professional fee, ostensibly tied to personal service rendered to the patient, and which through hospital cost-reimbursement funds, a category that wraps in such ineluctables as teaching and supervision of house staff and other personnel.

Dong, who is best known outside Stanford as coauthor of a recent science fiction thriller on artificial hearts, stopped doing heart surgery years ago because of "changing goals." He says he has a grand aim: "I want to reorganize the direction of this school. It's not going in the direction I've been raised to believe in—delivering first-quality, individualistic medical care." He also has a grand ambition: to enter "state or national" politics. "There are well-meaning people in legislatures," he explained in an interview, "but they don't have the expertise to know when they're being conned by people with apparently altruistic motives." To further his new ambition, he is currently going to law school in his free time now that he no longer performs much surgery.

From yet another quarter Stanford suffered the most telling blow to date in early September. Federal Medicare officials announced they would not pay Stanford $2.4 million in anticipated reimbursement. The Medicare fees that Stanford faculty received for their professional services and turned over to the institution were now to be considered "restricted funds" and deducted from the hospital's Medicare cost-reimbursement. Stanford is appealing the action but the medical center's finance director told the faculty that "our chances of a successful appeal . . . are not great."

One immediate effect of the Medicare bombshell was to wipe out the clinical faculty's accustomed end-of-the-year bonuses, up to 40 percent of base salary for the highest-paid specialists. That was the beginning of the end for the dean. Many of the clinicians were incensed; and since they do not generally

*(continued on page 741)*

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**References:**
1. Meyer, C.: American Folk Medicine. Scarborough, New York, Plum Books — New American Library, 1975, p. 208.
2. Data on file, MERRELL-NATIONAL LABORATORIES
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*(continued from page 740)*

consider Clayton Rich their staunchest ally and defender—a former clinical chief calls him "the dean for biochemistry"—they naturally blamed him.

On 3 November, with his future uppermost in his mind, Rich had an especially unpleasant task. He appeared before 350 Stanford medical students to tell them that tuition would jump next year by 27 percent for entering students (from the current $5388 to $7373 for the academic year) and 15 percent for those currently enrolled (up to $6373); and also that it will take longer to win a Stanford M.D. (a minimum of 13 quarters, or just over 4 years). The average attendance now for students in Stanford's unique, all-elective program is 12.9 quarters, but there has been a growing tendency for students to leave after 3½ years to take clinical clerkships elsewhere. The net effect of the tuition changes, after adding 9 percent annual inflation to next year's "catch-up" increase, will be to add $6500 to the cost of a Stanford medical education. And Rich had to admit he didn't know where the school was going to get additional student aid funds.

Although the increase would not place Stanford ahead of what many private medical schools levy, the students' response was predictably angry. They assumed, in part correctly, that they were paying for the Medicare disallowance they had heard about.

By the time Rich appeared before the students, President Lyman had received emissaries from the medical faculty. Consulting key faculty on his own, Lyman discovered a quiet mutiny. One faculty member later said: "It's not the style here to have open discussions and votes of no-confidence." In individual conferences, some of the most influential clinical chairmen are said to have imparted the same message: "Things can't go on like this."

Lyman got the message. On 8 November he announced Rich's resignation.

"It was clear there was going to be a confrontation within the school if I didn't resign and that I would need the substantial support of Lyman," Rich explained recently to *Science*. "Neither of us felt it would be the best course for the school at this point. . . . It's absolutely essential not to have the departments pulling in different directions and pointing the finger at each other."

Two days later the other shoe fell. The chief fraud and abuse official for Medi-Cal reportedly told Stanford officials in private the results of the double-billing investigation instigated by Dong and Weinmann. On the basis of a review of "effort report" forms, which are supposed to reflect how much time a faculty member spends in "direct patient care" of the "hands-on" variety, California officials are said to have concluded that there was double-billing of Medi-Cal over a 3-year span. One Medi-Cal official told *Science* that Stanford has also been informed that the state may seek restitution for the double-billed amount, which could amount to several million dollars. Crowley, the deputy dean, who was at the meeting, says he did not hear that message; but he and several other medical center officials acknowledge Stanford's vulnerability to the charge. "We may come to feel we used some funds we shouldn't have on the basis of those time reports," Rich said. A medical center lawyer added: "Our answer is that the [effort report] form wasn't very well designed.

### A Grocery List of Troubles

As the dean hinted last spring, government reimbursement difficulties are not the only ones that bedevil Stanford these days, nor even the thorniest. A grocery list of others would include:

- Declining demands for Stanford's services. Fewer patients are coming to Stanford's clinics and hospital. The hospital was budgeted for 188,000 patient-days last year but counted only 166,000. The trend is especially pronounced in the "community" beds of the hybrid teaching-community hospital, which account for about half the total. Last year the community beds were filled only somewhat more than 60 percent of the time. As Rich suggested, the growth of several fledgling prepaid health plans on the San Francisco Peninsula threatens to accelerate the exodus, since Stanford is too expensive a place for routine hospitalization under prepaid plans.

- Wretched town-gown relations. Last summer, at the urging of clinical faculty members, Stanford Hospital directors voted to close off hospital privileges for certain services—radiology, anesthesiology, and labs such as neurology, nuclear medicine, and cardiac catheterization—to community doctors not already on the staff. Access to inpatient beds would remain open to qualified outside clinicians "for the foreseeable future"—a phrase that despite repeated disavowals sounded to community physicians "like a week from Thursday," as one Stanford official put it. The decision angered and alarmed area doctors, especially the 120-doctor Palo Alto Medical Clinic group which sends patients nowhere else but Stanford. Many of these community doctors are Stanford-trained; they view the recent action as an abrogation of the university's promises back in 1959, when the medical school moved here from San Francisco, and 1968, when the university bought out Palo Alto's interest in the community hospital component. President Lyman and other Stanford officials have denied bad faith but they are clearly worried about the threats from community doctors to take their patients down the road to some quite respectable nonteaching hospitals where the welcome is warmer.

- Clinical facilities problems. According to James H. Stanford, the medical center's finance director, 20-

year-old Stanford Hospital requires more than $12 million in renovations (after just losing millions on a new addition in cost overruns and delays) to meet accreditation and licensure standards. Yet the hospital has no separate endowment, he said, and the time is not propitious to be launching any community fund drives "given the current [town-gown] tensions." Moreover, Stanford is worried about the future of another vital resource, the county-owned Santa Clara Valley Medical Center. A quarter of Stanford's medical students and an equal proportion of its residents rotate through Valley Medical Center at any one time. But Proposition 13 has frozen salaries at the public hospital, causing an exodus of nurses and occasional shutdowns of intensive care units, and no one is sure how California governments are going to meet next year's Proposition-13 crunches. More ominously, the conservative fiscal mood impinges on the chances of an $84-million reconstruction program for the county institution, without which it cannot maintain accreditation and licensure.

Stanford University can't do much about the San Andreas Fault except to try to make its buildings "earthquake-proof." Likewise, Stanford University Medical Center cannot wish away inflation, competition, Proposition 13-ism, or lurking threats such as federal demands for more primary-care doctors or the Carter Administration's contemplated cutbacks in medical school capitation grants and research funds (see *New York Times,* Sunday, 3 December, p. 1). That means the school and hospital face some sort of fiscal earthquake-proofing; or as the exiting dean characterizes it, "significant reprogramming and rebudgeting."

As any initiate of faculty politics knows, those are fighting words. In terms of the medical school, the sibling rivalry is between those who see patients and those who do not—the clinicians and the researchers—and also between "have" departments, such as surgery and radiology, and "have-nots," such as pediatrics and many subspecialties.

The struggle has been a long time coming, arguably since 1959, when Stanford Medical School moved from San Francisco to Palo Alto and was reincarnated as the very model of a research-oriented medical school. For 10 years the decision paid off stunningly; by 1969 federal research funds supported 60 percent of the budget. But as everyone knows, or should have known, what goes up must come down. By 1974 research funds paid 41 percent of the faculty's salaries; since then the ratio of research-derived to clinically derived support has swindled from 1.5 to parity.

For years Stanford weathered the shift by virtue of its complex administrative structure, which allowed the dean to reallocate revenues according to his priorities. But such a structure is vulnerable at a time of across-the-board and increased fiscal accountability, a lesson that Stanford has seemed slow to learn. Rich had hoped to meet the emergency without much structural reform. Lately he had been pushing for a plan to organize the clinical faculty into a large corporate group practice, apparently on the theory that government agencies and statutes, such as a California law against "the corporate practice of medicine" that Stanford is accused of violating, would thereby be satisfied. Under such a group practice, the faculty would technically no longer be "on salary" from the university, but the dean, as executive head of the corporation, might presumably maintain a good deal of redistributive discretion.

With Rich's departure that resolution of the problem may be down the drain too. The more powerful clinical chiefs, such as heart surgeon Norman Shumway, are said to be designing departmental group practices that would keep firm control of departmental revenues.

The implications of these plans are not lost upon basic researchers, who of course see no patients, nor upon have-not clinical departments that depend on cross-subsidization from their more prosperous brethren. "Basic research just can't survive if the dean loses his discretion to shift funds," argues one of the nonclinical department chiefs, Eric Shooter of neurobiology. "We aren't exactly the poor relations but we've got to have some subsidy. There has to be a transfer from the clinical side to the basic side." Resentful of the surgeons' boasts that they bring in the lion's share, and groping for solutions, Shooter even suggests plaintively that researchers "get some kind of incentives too, like some part of the indirect [research grant] costs coming back to the investigator as an incentive to write the next grant." It is an idea unlikely to excite the interest of the Department of Health, Education, and Welfare.

Creeping unease about a change in Stanford's mission—a natural and perhaps ineluctable consequence of the funding and power shifts within the school—is emerging in other contexts these days. Last summer Nobel Laureate Arthur Kornberg, the faculty's most forceful exponent of the Stanford status quo, complained in the alumni magazine about the "erosion of our scientific enterprise" and the "inordinate control over school policy" exercised by clinicians just because they bring in "a major fraction of the school's budget."

"I am concerned," Kornberg wrote, "when there is a proliferation of teaching, clinical service or administrative activity far beyond what is appropriate for an institution with a major mission to create new knowledge."

And the ideological debate extends beyond fiscal power. Two years ago Kornberg and a number of like-minded faculty concluded that Stanford was admitting far too many students who were more interested in practicing medicine than in "creating new knowledge." As Shooter put it recently, echoing many others, "In the early seventies the admissions committee went overboard in the admission of students who knew from the day they came that they wanted to be general medical practitioners. Stanford is not the place to train that kind of individual."

Those who felt this way engineered a restructuring of the school's admissions procedure that many believe has corrected the trend, though one department chief recently lamented: "Lately I find students drifting toward the practice of medicine. I don't object to that," he added quickly, "but I thought originally that Stanford was more research-oriented."

There is some evidence, however, that sharply calls into question whether Stanford Medical School has ever turned out a preponderance of scientists and academicians, even in the biomedical boom days of the sixties. Lawrence Horowitz, a staffer for Senator Edward M. Kennedy's Senate Health Subcommittee, did a survey of Stanford alumni while he was a Robert Wood Johnson Clinical Scholar at Stanford from 1974 to 1977. Horowitz found that the "new," post-1959 Stanford Medical School did indeed graduate significantly more M.D.'s who ended up in medical research and teaching than the old San Francisco-based school had. Even so, he found, only one out of five Palo Alto-period alumni became full-time medical school faculty members. Moreover, a majority of those who graduated between 1960 and 1972 do no medical research, and a majority of those who do spend less than a quarter of their time at it.

"If it is clear that the majority of Stanford students do not want to become scientists or do research in a meaningful way," Horowitz asked in an article published last summer, "then does it not follow that Stanford's education is unbalanced because of a research and subspecialty bias?"

The "Horowitz Report" is not much talked about at Stanford Medical School; out of two dozen interviews with *Science* recently, no one brought it up spontaneously and most brushed it aside when it was mentioned. Last month, however, as if in rebuttal to Horowitz's question, a curriculum reform committee chaired by Robert A. Chase, a surgeon, said the school should take firm steps to ensure more research-oriented and scientifically competent graduates. Specifically, the committee frowned on the growing tendency of Stanford students to get through medical school as rapidly as possible and get on to clinical training; to reverse this state of affairs, it recommended that all students be required to write and defend a thesis, and to stay at least 13 quarters to do it.

The recommendation has not yet been acted upon by the school's faculty senate. So far its critics have been found mostly among the students, who question whether the thesis requirement will produce better doctors, diminish diversity among the student body or even, given its coercive aspect, lead to scientific competency and useful work. Proponents tend to take the attitude that it matters not one whit what the current students think: in the future, if the thesis requirement is adopted, Stanford will attract only those students who *want* to engage in "a scholarly investigative experience." The students' self-appointed ombudsman and faculty spokesman, William Creger, sees it a different way. Creger, who was dean of student affairs at the medical school until he had a falling out with Rich over admissions procedures and other matters 2 years ago, calls the proposed thesis requirement "more depressing than a required religion" and adds caustically: "I think we've got some scientists around here who feel threatened because students don't think they're the only gods any more."

Apart from the particulars of the "thesis" debate, however, the interesting thing about the Chase committee's report is the set of underlying "assumptions" which the authors took the trouble to lay out. Two of the 13 assumptions stand out:

- "Stanford should specifically address the public's need for medical scientists;" and
- "It should not be Stanford's function to meet specific societal needs through production of the number and proportion of various kinds of M.D.'s needed in today's maldistributed pool."

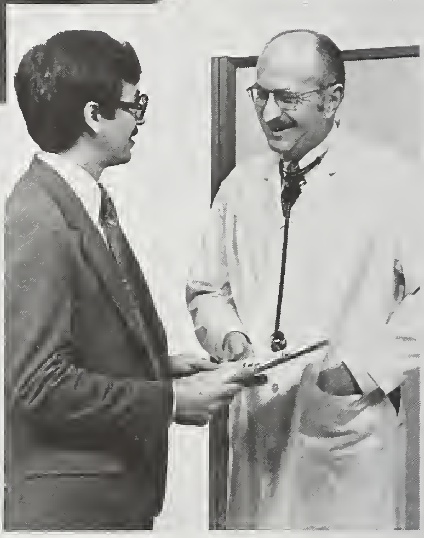
If this language sounds a tad defiant at a time when HEW Secretary Joseph A. Califano is telling the Association of American Medical Colleges to curb "the runaway growth of specialists and subspecialists," the implication is entirely deliberate. In discussions of the Chase committee's report among the faculty leaders recently, someone reportedly pointed out that the school should consider how such statements would read "on the front page of the *New York Times*." But after due consideration, the faculty decided to let it stand.

The document is merely symptomatic, in an unusually stark way, of the tensions within academic medicine in the late 1970's. Stanford traditionalists see their plight as tragic and their resistance as noble. But even one of Stanford's own, health economist Victor Fuchs, sees it in quite a different light. Speaking before the New Orleans convention of the Association of American Medical Colleges in late October, Fuchs said:

"Even a sympathetic, friendly observer can't help but get the impression that academic medicine's interest in health policy begins and ends with two commandments:

"First, 'give us money,'

"Second, 'leave us alone.'"



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# The President's Page

In testimony submitted to the Program Review and Investigation Committee of the Connecticut State Legislature on September 27, 1979, Mr. Stephen A. Harriman, Director, Division of Medical Quality Assurance submitted suggestions on behalf of the State Department of Health Services for consideration as to how that committee of the General Assembly might structure the regulation of occupations and professions which are licensed by the Department of Health.

In his concluding remarks Mr. Harriman stated, "The era and times have long since passed when we can hold to the maxim: that what is good for business is good for country or paraphrased, 'What's good for the profession is good for society.'"

He went on to say, "Professionals in most occupations usually organize into groups and associations to promote their own interests. This is as one might expect, however, it would be naive to conclude that the interest and needs of the professions are always in parallel with the public's best interests. Issues, such as consumerism, accountability, restraint of trade, competition and innumerable others are at the fore-front of today's concerns, and it is recommended that one incorporate these factors into any structure which is recommended by this Committee."

Mr. Harriman then suggested that the powers of the board or commission should be limited to that of: 1. reviewing and commenting to the Commissioner of Health our proposed regulations and, 2. advising the Commissioner with regard to examinations the Department administers to its respective professions. Furthermore adjudication of formal allegations referred against a licensee by the Commissioner of Health Services should also be his responsibility, and any member of a such commission could have certain legal powers such as administering oaths, issuing subpoenas, compelling testimony as well as the implicit power to resort to the Superior Court for enforcement of an order. And finally, Mr. Harriman suggested that each board or commission be comprised of not less than one-third of its number as members of the public who have had no professional affiliation with any profession for three years or more preceding their appointment to the Board of Commission. In addition, he recommended that no professional member of such a board or commission within the department could presently be an officer in any professional organization nor have served in such a capacity in the immediate three years prior to appointment to the board or commission.

At first glance the recommendations appear to be motivated solely by the desire to open the professions to greater public scrutiny and accountability; however, on closer examination there's also a subtle innuendo that can easily be construed as nothing less than a presumptuous indictment of all of us as professionals in the health care delivery system.

Any society incorporating into its structure committees whose prime functions relate to education, patient care, peer review, public health, quality control and cost containment is more than merely a self serving organization. The very nature of physicians' duties require that they spend countless hours dealing with and helping solve problems faced by society as a whole. If that is so, how can they also be devoid of a sense of social justice and of a sense of responsibility? To summarily disqualify medical leadership simply because of its simultaneous involvement with the profession as an organized entity is to prejudge integrity pejoratively. To even intimate that many of our colleagues who have served so honorably in judicial capacities dealing with similar matters within the organized entity will suddenly have lost all of their objectivity when appointed to a board or committee set up by the state for exactly the same purpose is not only insulting, it's stupid!

Those chosen to serve on committees dealing with disciplinary matters are picked because of their integrity, honesty and objectivity. The so called "conspiracy of silence" is a thing of the past. When professionals fail in their ability to deal punitively with recalcitrant members it's with a deep sense of bitterness and frustration mainly because the legal system is so weighted in favor of the recalcitrant. To intents and purposes the disciplinary authority of such committees has been so diluted and emasculated as to be almost nonexistent.

What governmental agencies must understand is that what is needed is greater not-less authority by the profession to deal with disciplinary matters concerning its members. If this were to take place and it was accompanied by more open proceedings and with outside participation by distinguished jurists, people at long last would become cognizant of the fact that the profession has concern for the public welfare.

Any action taken by the legislature attempting to protect the public, but which simultaneously bypasses the knowledge and expertise of our profession would be a mistake, since by isolating physicians from the discipline of their own profession and circumventing the peer review mechanisms now functioning within organized medical societies, the legislators would be defeating the very purpose for which the legislation was designed in the first place, i.e., the protection of the patient.

Edward A. Kamens, M.D.,
*President*

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# Reflections from the Dean's Office

## The Cheerful Physicians

ROBERT U. MASSEY, M.D.

Like the doublets in the prose of the *Religio Medici,* Sir William Osler and Sir Thomas Browne go together. The two were born 244 years apart, yet for Osler the *Religio* was his *comes viae vitaeque,* his constant companion. He bought his first copy in 1867, and it was that copy which lay upon his bier on New Year's eve, 1919.

In his farewell address before sailing for England and Oxford in 1905, William Osler recalled that three ideals had guided his life: "to do the day's work well and not bother about tomorrow," the second, "to act the Golden Rule, so far as in me lay," and the third was equanimity. The first was the theme of his address to Yale students in 1913: " . . . only for this day are we to ask for our daily bread, and we are expressly bidden to take no thought for the morrow." Later came the well known line, "The load of tomorrow added to that of yesterday, carried today, makes the strongest falter." To face the day without anxiety for the future or remorse for the past requires a faith in the goodness of nature, a cheerful confidence that all things will work out if the work at hand is well done.

The Golden Rule has to do with tolerance and making allowances: "Deal gently then with this deliciously credulous old human nature in which we work."

Most of us still have that gift from Eli Lilly, our graduation copy of Osler's *Aequanimitas,* and although we have forgotten much of it, the title has returned in a thousand difficult times.

"In the first place, in the physician or surgeon no quality takes rank with imperturbability," which Osler described later as "coolness and presence of mind under all circumstances, calmness amidst storm, clearness of judgment in moments of grave peril, immobility, impassiveness, or to use an old and expressive word, 'phlegm.'"

Browne too, living in an unkind and stormy age, had faith in the essential goodness of the world, a cosmos which revealed the art and the wisdom of its Creator ("there are no *grotesques* in nature"):

> "Thus there are two bookes from whence I collect my Divinity; besides that written one of God, another of his servant Nature, that universall and publik Manuscript, that lies expans'd unto the eyes of all; those that never saw him in the one, have discovered him in the other."

Of all times the seventeenth century with its wars of religion must have been one of the most bigoted; against that, Thomas Browne's tolerance comes as a flash of sunlight through lowering clouds:

> "I could never divide my selfe from any man upon the difference of an opinion, or be angry with his judgment for not agreeing with mee in that, from which perhaps within a few dayes I should dissent my selfe,"

and later,

> "For my conversation, it is like the Sunne's with all men, and with a friendly aspect to good and bad."

Browne's equanimity is the substance of his long life, that of a competent good natured general practitioner of Norwich. He lived and worked through Civil War, Cromwell's rule, and the Restoration, faithful to his king and Church. For this he was knighted by Charles II in 1671. In spite of the painful years of puritan rule, Browne never mentions them except in a few lines in the introduction to the *Religio* and in private correspondence. His friend, John Whitefoot, said of him that,

> "He was never seen to be transported with mirth or dejected with sadness; always cheerful but rarely merry, at any sensible rate; seldom heard to break a jest, and when he did he would be apt to blush at the levity of it. His gravity was natural, without affectation." He was certain in company with the fourteenth century anchoress of Norwich, Lady Julian, that, ". . . all shall be well and all shall be well, and all manner of thing shall be well."

To understand Browne's philosophy requires more knowledge of the intellectual currents of seventeenth century England than most of us have. His prose, which has been described as Augustan, need not be dissected to be enjoyed. It is not difficult, and his nature shines through it, just as Osler's character is manifest in his essays and addresses.

They were not unlike. Osler was the better scientist, even allowing for his century, and Browne the better writer. Both men were tolerant humanists, compassionate, imperturbable, essentially conservative, and consciously concerned with high principles and ultimate values. After reading one or the other, we become aware with a start that they were not companions in the flesh.

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ROBERT U. MASSEY, M.D., Dean and Professor of Medicine, University of Connecticut School of Medicine, Farmington.

# In Memoriam

**BUOL, ROBERT S.,** Harvard Medical School, 1923. Dr. Buol was a pediatrician in the Hartford area since 1925, and was a former Chief of Pediatrics at New Britain General Hospital. He also served as physician of the Health Department for 26 years until 1963, retiring from active practice in 1965. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Buol died September 26, 1979, at the age of 81.

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**CHIARAMONTE, CAJETAN T.,** Long Island College of Medicine, 1926. Dr. Chiaramonte was a dermatologist in the Fairfield area since 1964. He served as honorary dermatologist at Danbury Hospital and was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Chiaramonte died June 18, 1979, at the age of 77.

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**ELLIS, LYLE G.,** Jefferson Medical School, 1920. Dr. Ellis was a general practitioner, specializing in industrial medicine and surgery, in the Hartford area since 1942, and was a past medical director of the Travelers Insurance Company. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Ellis died August 13, 1979, at the age of 83, in Rocky Mount, North Carolina.

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**FAY, WILLIAM J.,** Harvard 1914. Dr. Fay was a surgeon in the Hartford area since 1916. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society. Dr. Fay died April 2, 1979, at the age of 90.

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**GETTINGS, JAMES A.,** Jefferson Medical School, 1916. He practiced medicine in New Haven from 1919 until his retirement in 1976. He also retired in 1976 as the surgeon for the New Haven Fire Department, a post he held for more than 30 years. He was a past president of the New Haven County Medical Association and was a World War I Army veteran. While in service, he received the Purple Heart, the Silver Star with clusters and was recommended for the Distinguished Service Cross, and was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Gettings died September 6, 1979, at the age of 88.

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**NAROWSKI, CECILIA A.,** Temple Medical School, 1954. Dr. Narowski was a pediatrician in the New Haven area since 1955. She was a Waterbury school medical advisor and examiner in 1977 and 1978, and was a member of the Valley Board of Health in 1976 and 1977. Dr. Narowski was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Narowski died September 28, 1979, at the age of 52.

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**NICHOLSON, RICHARD E.,** Tulane Medical College, 1942. Dr. Nicholson specialized in industrial medicine in the Hartford area since 1945. He served in the U.S. Army Air Force from 1943-1946 and was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Nicholson died in July, 1979, at the age of 61.

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**OPSAHL, JEANETTE C.,** University of Alberta, Canada 1954. Dr. Opsahl was a internist in the New Haven area since 1957. She was a member of the New Haven County Medical Association and the Connecticut State Medical Society. Dr. Opsahl died August 29, 1979, at the age of 62.

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**ROGOL, LOUIS,** Long Island College of Medicine, 1933. Dr. Rogol was a general practitioner in the Fairfield area since 1934. He served in the Army Medical Corps from 1942 to 1946, in England, North Africa and Italy, retiring with the rank of major. Chief of medicine and chief of staff at Danbury Hospital, he was instrumental in the establishment of the Danbury Heart Association. He retired from active practice six years ago to become medical consultant for the division of hospitals of the state Department of Health, and five years ago he became medical director of the Federal Correctional Institution. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association. Dr. Rogol died August 27, 1979, at the age of 71.

# The Legal Rights of Minors in the Health Care Process II

JOSEPH M. HEALEY, J.D.

Among the questions left unanswered in the abortion cases of *Roe v. Wade*[1] *and Doe v. Bolton*[2] was the extent to which a minor woman was entitled to the same rights as an adult woman. This question was presented to the United States Supreme Court during the 1975-76 term in the cases of *Planned Parenthood of Central Missouri v. Danforth*[3] and *Bellotti v. Baird*[4]. In the former case, the Court rejected as unconstitutional a blanket provision requiring the consent of a parent or person *in loco parentis* before an abortion could be provided to an unmarried minor during the first 12 weeks of her pregnancy. The Court refused to accept the granting of an unconditional and potentially unjustified veto by a 3rd party of the decision by a minor and her physician to terminate her pregnancy. The Court pointed out that it was not suggesting that every minor regardless of age or maturity was entitled to abortion. It implied that there were situations in which justification for the restriction of a minor's decision existed. However, the Court failed to clearly delineate them.

The companion case, *Bellotti v. Baird* presented similar issues involving a minor's right to abortion without parental consent. This case, however, was remanded to the Federal District Court in Massachusetts for further hearing since the Supreme Court concluded that the statute was susceptible of a construction which would avoid or modify the federal constitutional challenge. The Supreme Judicial Court rendered its decision which did not avoid the constitutional issues and *Bellotti v. Baird* returned to the United States Supreme Court.

In the lead opinion of an 8-1 decision[5], Mr. Justice Powell pointed out that there are three chief reasons why the constitutional rights of children cannot be considered the same as adults in all circumstances: (A) the vulnerability of children and their need for protection; (B) their limited ability to make critical decisions in a mature manner; and (C) the importance of the parental role in the rearing of children. These reasons are important and need to be examined and applied in specific contexts. Abortion is a particularly sensitive area and there must be limits to justified interference with a minor's decision to abort. If a minor is required to obtain parental consent before abortion, the minor must also have access to an alternative process through which authorization can be obtained. This process need not involve a court of general jurisdiction, but may involve a juvenile court or an administrative agency. In this process, a pregnant minor is entitled to show that (1) she is sufficiently mature and sufficiently informed to make an abortion decision with her physician independent of her parents' wishes or (2) that even if she is not able to make this decision independently, an abortion would be in her best interests. The proceeding in which this takes place must be completed with anonymity and with sufficient speed as to allow an opportunity for an abortion if approval is granted.

Following its lead in *J.L. v. Parham,* the Supreme Court has rejected the claim of unqualified right by either parent and minor. If there is to be state regulation of the minor's abortion decision, there must also be provision for a mechanism to allow mature minors and minors for whom abortion is in their best interest to obtain authorization. The degree of division in our society over both abortion and the concept of minor's rights is so strong, it is likely that obtaining the balance of rights in this sensitive area will not easily be achieved.

## REFERENCES

1. Roe v. Wade, 410 U.S. 113 (1973)
2. Doe v. Bolton, 410 U.S. 179 (1973)
3. 428 U.S. 52 (1976)
4. 428 U.S. 132 (1976)
5. ____ U.S. ____, 47LW4969 (1979)

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JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut, School of Medicine, Farmington.

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# Month in Washington

## National Health Insurance

Sen. Kennedy and Rep. Henry Waxman have introduced the sweeping NHI plan they and organized labor want Congress to adopt. Fifty-eight House members lined up with Waxman on the bill; seven Senators joined Kennedy.

Kennedy made clear that the breach between his forces and the Administration on national health remains unbridged. President Carter's plan is "unacceptable," Kennedy told the Senate.

"I hope now that the debate can begin in earnest," said Kennedy. "This can still be the National Health Insurance (NHI) Congress."

Waxman said in a speech to the House that "our bill will benefit the doctor and the consumer by assuring that medical treatment is based entirely on sound medical practice, not on one's ability to pay for needed treatment."

Kennedy revealed last May the outline of the new plan drafted by his staff and organized labor experts. More than a year ago, the Senator and his labor cohorts broke with the President on NHI, chiefly because Carter wanted Congress to implement a NHI program in stages, whereas Kennedy thinks Congress should approve everything right away.

One of the reasons former HEW Secretary Joseph Califano was reportedly fired from the Cabinet was his attempt to reach an accommodation with Kennedy on NHI, a detente that apparently neither side wishes at this time.

The Kennedy-Labor bill sets forth an ambitious national scheme combining private and federally-financed insurance with rigid budget controls. Cost is estimated at well over $30-billion annually, by far the most expensive NHI plan before Congress.

Borrowing a leaf from President Nixon's NHI plan, Kennedy would mandate employers to provide comprehensive insurance for workers. The government would pick up the tab for the aged and the poor. Prospective budgeting for hospitals and negotiated fee schedules for physicians would be the principal cost control features. A national health budget would be set.

Senators backing the Kennedy plan at introduction were Harrison Williams (D-NJ), Alan Cranston (D-CA), Jacob Javits (R-NY), Howard Metzenbaum (D-OH), Claiborne Pell (D-RI), Donald Riegle (D-MI), and Lowell Weicker (R-CT). All except Weicker are members of the Senate Human Resources Committee, home of Kennedy's Health Subcommittee.

"Sen. Kennedy's bill is remarkable in a number of ways," the AMA commented.

"In an era of destructive inflation, he would add billions to the nation's health care costs.

"In an era when Federal regulation is regarded as an impediment to economic and personal freedom, he would add new layers of health care regulations.

"In an era when the demand for health care is growing, he would subject the nation to the possibility of health care rationing.

"Sen. Kennedy's program, while it gives the appearance of being based on the private sector, would reduce insurance companies to little more than administrators of the plan. Furthermore, his plan ignores the current realities of the U.S. economy and the long-range forecasts of continuing inflation and would impose an additional $30-billion burden on the nation.

"The AMA will continue to support an expansion of adequate basic and catastrophic insurance through private sector programs."

* * * *

Shortly after Kennedy's NHI bill introduction President Carter sent Congress his "National Health Plan" calling for employers to provide comprehensive insurance for workers and establishing a "Healthcare" umbrella plan for the aged, disabled, poor, unemployed and anyone who can't get private health insurance.

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*Prepared by the Washington, D.C.*
*Office of the American Medical Association*

The bill was introduced in the Senate by Sen. Abraham Ribicoff (D-CT), and in the House by Reps. Harley Staggers (D-WV), Chairman of the House Commerce Committee; Charles Rangel (D-NY), Chairman of the House Ways and Means subcommittee on Health; and James Corman (D-CA), a member of the Ways and Means Committee.

The Administration's bill is the last of the major national health insurance (NHI) measures to be introduced, trailing two weeks behind introduction of Sen. Edward Kennedy's NHI bill and about a year later than originally promised.

Carter said he was "determined" to secure action on NHI, implying that he could supply better leadership on the issue than Kennedy, his unofficial threat for the presidential nomination.

But the odds seem stacked against this Congress acting on a large, expensive NHI plan. Only an alliance with the Kennedy forces would appear to give the Administration bill even a remote chance, and Carter made it clear he is in no mood to bridge his NHI difference with Kennedy and his labor backers.

The Administration plan provides for NHI to be implemented in stages by Congress, eventually reaching a universal comprehensive program. By contrast, the Kennedy bill would have Congress enact the entire package at once. This is the major difference between the two bills.

The first phase plan submitted by the President would take effect starting in 1983. Cost was estimated at $18.2 billion to the federal government and $6.1 billion in the private sector.

The bill mandates employers to provide coverage for all full-time workers and their families. Catastrophic coverage would apply after the first $2,500 in expense. Employers would have to pay at least 75 percent of the premium costs.

Required benefits are similar to those under Medicare, but broader. Unlimited hospital inpatient and physician services would be furnished. Complete prenatal and delivery care for mothers, one year of infant care and preventive services for children through age 18 would be provided.

Medicare and Medicaid would be lumped into a broad, new federal health insurance program called "Healthcare." People unable to obtain private insurance at reasonable costs could purchase the Healthcare insurance. This plan would be financed with Social Security money, general revenues and state government funds. Medicare and Medicaid benefits would become identical, but the two programs' operations financing would remain essentially the same.

Hospitals would be reimbursed along the lines of the Administration's Hospital Cost Containment plan. Physicians under Healthcare would have to agree to a fee schedule as full payment. The schedule would not be mandatory for the private system, but "advisory."

* * * *

## FTC

The Federal Trade Commission's (FTC) controversial forays into the medical field have come under strong attack in Congress and in the Courts.

Spurred by business and professional antagonism toward the FTC, a House appropriations subcommittee has approved a money-cut halting FTC's so-called consumer protection investigations and two major anti-trust investigations. Sen. James McClure (R-ID), has introduced an amendment that would exempt professional associations from the scope of the anti-trust laws. Support is building in the Senate for a Congressional veto power over FTC decisions.

The FTC case before the U.S. Court of Appeals in Washington, D.C., concerns its trade regulation rule lifting all professional and state restrictions on the advertising of eyeglasses and ophthalmic services. One provision requires that consumers be provided with copies of their prescriptions after eye examinations.

Appealing the rule to the Court was the American Optometric Association, nine states, and the American Medical Association. The chief thrust of the complaint by the lawyers, including Newton Minow, counsel for the American Medical Association, was that the FTC was improperly pre-empting state laws and that the agency does not have statutory authority to move against non-profit associations.

Minow a few days later testified before the Senate Commerce subcommittee on Consumer Affairs which had launched a week of hearings on the FTC and complaints about it. He told the Senators that the AMA agrees that misleading advertising should be considered unlawful. The AMA also agrees that consumers should be provided copies of their eyeglass prescriptions, Minow said.

But, Minow continued, "the FTC should not be allowed to override the decisions of the duly elected representatives of the people of each state as to what laws are in the best interest of the people of that state" and the FTC should not be permitted "to prevent professionals—in this case, physicians from voluntarily associating together to speak out against false or deceptive advertising which harms the patient."

"We are witnessing an unprecedented effort by a federal agency to redefine the fundamental relationships of our system of government. The FTC, already cloaked with exceedingly broad powers, is now asserting the authority to set aside any state law it doesn't like," Minow declared.

# The Physician and the Elderly

FRANCIS J. BRACELAND, M.D.

*And how is it with aging lawyers, Pontiffs, augurs and philosophers? What a multitude of things they remember. Old men retain their mental faculties provided their interest and application continue.*
*— Cicero De Senectute VII 21-23*

Physicians are being importuned from many directions to interest themselves in the elderly segment of our population. The Secretary of HEW, at the most recent meeting of the Association of American Medical Colleges, told its members that [1]"By the year 2030 we expect 18% of the U.S. population to be over 65, up from 10%. This means more emphasis on chronic rather than acute conditions, more attention to palliative and rehabilitative as opposed to curative medicine, and more need for long term care as opposed to acute care settings." He noted further somewhat ruefully that, "Thousands of students are graduated without having visited a nursing home or taken courses in the special health problems of older people."[2]

A few months later the well-known Dr. Irving S. Wright wrote in the same vein: "We are in a new world, never before has 10% of a major population group been more than 65 years of age. In the past it has been considered desirable to live to be old but now we find ourselves unprepared to meet the problem." The aged, "unlike the young, do not recover or die quickly but live on for months or years requiring more hospitalization time . . . and further require an approach and kind of care that differs from what physicians of this technical age are presently being trained to give."

Writing at the same time the distinguished Dr. Paul Beeson[3] recalled that he had spent most of his professional life in medical education, but recently he had served on a committee of The Institute of Medicine which was formed to have a close look at how the medical problems of the aged were being dealt with and he was disturbed by what he saw. Medical schools and teaching hospitals, he said, were paying too little attention to what was going on about them. What the elderly needed and what was being slighted was a continuing lifelong care of people with chronic progressive disabilities. He realized the difficulties encountered by today's medical educators and he offered several suggestions to remedy what he feels is a huge deficit in our present day medical care system. Interestingly enough, in addition to the chorus of concern voiced by these prominent men, a recent meeting of the American Medical Students Association held a workshop on "The Health Care of the Aged." They, too, pointedly noted that the curricula of American Medical Schools are sadly wanting in that regard.

We could go on and on and recite from the various concerns of outstanding individuals interested in the elderly both medical and lay, but it is obvious that some action is needed. Mindful of the story of the alcoholic derelict who was on trial before a judge who gazed at him sternly and said, "Do you realize you were brought here for drinking?" He said, "Fine, Judge, let's get on with it." Perhaps we too are being gazed at sternly and being judged and had better get on with our attention to and treatment of this rapidly graying population, for we as physicians are evidently being called to account.

Geriatrics which presently has acquired the status of a special interest is not as yet an isolated specialty with its heirarchy, its Boards and its specialty examinations. This is fortunate for physicians from various specialties have important contributions to make to it. Though aging is an important and intrinsic part of the life cycle and is being experienced by larger numbers of individuals today, it is still feared and denied by many. There is a form of mythology which has developed about the thought of growing old which sees it as a gray shadowy end of the line in which one slowly but surely loses one's best self and one's enjoyment of life. This outlook upon aging has created an unnecessary fear of it and has contributed to the negative and somewhat hostile attitude with which it is sometimes regarded. Unfortunately some physicians are not free of the taint of this negative

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outlook. Today ours is a youth culture and is reminiscent of what Hazlitt must have thought when he wrote: "The young are prodigal of life from a superabundance of it; the old are tenacious of it on the same score because they have a little left and cannot enjoy even what remains of it."

The ability to enjoy what remains of life—these are unique personal desiderata, growing larger in scope now that longevity is the lot of the many rather than of the few. It also enters the list of major social problems due to changing age distributions, the complexity of modern life with its personal and collective dangers, and even the mobile family structure itself. However, more than just a long life is needed for as Thomas A'Kempis observed, "It is vanity to desire a long life without caring whether it be a good life or not."

Stereotypes of differences in ages ran rampant a decade or two ago. Adolescents were designated as rebels and they in turn characterized people over thirty as untrustworthy. This latter image has eased a bit but the one concerning old age has not fared so well. There are still those in this present culture who see old age as a disaster and who visualize the elderly as poor, isolated, sick and useless, or on the other hand as rigid, powerful, unpleasant and reactionary. In either instance it makes the natural phenomenon of aging seem particularly unattractive. Yet 95 percent of the aged do not conform to these stereotypes and less than 5 percent of them require custodial care.

Fortunately, by now many of the unhealthy attitudes about aging are slowly being dispelled but, unfortunately, there is still in some spots a form of gerontophobia which is unpleasant and ill-advised.

*Who are the elderly?* One cannot generalize about them. They are an amorphous group; some are rich, more are poor, some are beloved, some despised; some are happy at home, some are enjoying sun cities; others are completely alone and have no one. Some are settled into fixed ways and are reluctant to change. Some have mellowed with age; some have become crotchety and seem to regard their age as permission to say what they think without stopping to think. Many others go on their way confidentially as they always have and at any one moment 95% of those over 65 live in the community.

Hippocrates wrote, centuries ago, that change, especially major change, was responsible for disease and sages have since pointed out that changes in one's environment demands new adaptive reactions, and disease is a consequence of inadequacies in these adaptive responses. One can have no doubt but that change today is all pervasive and in fact everything that the elderly held dear and sustaining has been challenged and altered. Attitudes toward religion, morals, ethics, family, marriage and work habits are vastly changed. One need only remember that in the lifetime of many of the elderly they have seen means of transportation change from horse cars to the advent of wide bottom jets and Concordes.

*Why do people get old?* The process begins at birth but we don't seem to start to worry about it until we get into the fifties. There are numerous theories about the aging process, probably none of them correct, for the intrinsic process still is not clear. Whether it is due to a gene or to the fact that fibroblasts cannot continue to divide indefinitely or whether it is due to problems with DNA and is or is not definitely programmed is for the researchers to finally decide. Only this we know—there comes a point in life when the tissues and energy reserves cease to expand. Physiologically there is a gradual impairment of homeostatic capacities; a maximal point of development is reached; an acme and then a gradual decline. Somewhere between these points some degenerative process has supervened and old age is upon us. The period is poorly marked and uncertain. It is frequently determined by the observer, by the measuring rod used, or by the purposes of the evaluation. The deciding factor can be physiologic, industrial usefulness, or the socio-economic or familiar attitudes operative in the culture rather than the exact chronological age of the individual. The idea of chronologic aging, i.e., measuring one's age by the calendar years he has lived, Butler[4] calls the myth of aging itself; for there are great differences in the rates of physiologic, chronologic, psychologic, and social aging from person to person, and also within the same individual. Aging then is a developmental stage of the human organization. Because the culture extols growth and progress, little value is given to the wisdom and experience of the aged. Elders have contributions to make, not only in intellectual circles but also in areas requiring the rapidly dwindling skills of equanimity, grace, and manners.

Bernice Neugarten[5] notes that, "In modern America it is not only biological timing that has become different: for example puberty comes earlier than before for both sexes and, although the data are less clear cut, that the climacterium comes later for women, or most dramatic biological change of all—that most people now live into old age." She continues, "Because highly educated people live longer than the average, those readers of this (her) paper who have reached 65 can look forward to reaching 80 or 85 as is especially true for women, and the younger readers can expect to live even longer."

The thought of old age frightens many people. The idea of being obliged to slow up, to retire, to change and perhaps become more dependent on others physically, emotionally or financially is not an enticing thought, especially for those who have led active independent lives. There are fears of loss of occupation, curtailment of income and even restrictions of independence.

Some men who have been stalwarts and the source of strength for the family will have to be careful lest they surprise themselves and others by becoming peevish and childish due to their changes in status and the physical changes which inevitably must come. The fear of being unable to take care of one's self and of becoming a burden to others is a phobia which might intrude itself no matter how well off financially one may be.

Personally, I agree with Nouwen,[6] a theologian philosopher, that, "Aging is the turning of a wheel, the gradual fulfillment of the life cycle in which receiving matures in giving and living makes dying worthwhile. Aging doesn't need to be hidden or denied but can be understood, affirmed and experienced as a process of growth in which the mystery of life is slowly revealed to us. Without the elderly we might forget we are aging. The elderly are our prophets; they remind us that what we see so clearly in them is a process we all share."

Actually not all of the aging process is grim, or if it seems to be, one can be pleasant about it; some even take pleasure in even accomplishing it. In our culture fear of aging is frequently influenced by fear of not being able to live up to expectations of an environment in which "you are what you can produce." Society's stereotyping robs the aged of their individuality. The images given of an old person, garrulity, reminiscences, and a rocking chair are hardly enticing and they help to permit us to forget the aged. Some believe that discrimination against the elderly reflects our own fear of it. Cassell[7] states that there is "little wonder that the aged trouble us. When we see a group of young people with pleasure we see an aliveness and joy, a magic vitality that is as much a flowering of the body as the person within. But when we find special pleasure in an old person shining through, the bodily state is secondary. We appreicate the rareness of success in age. We wonder how the old man did it and whether or not we can do it. If we really want to know, Nouwen said, "We shouldn't turn to scientific treatises but rather to philosophy and seek as much help from the ancients as the moderns." What he is saying, I take it, is that it is the patient's spirit and his inner self that is shining through. Science has stopped short of reminding us that the solution of some of our problems lies within ourselves.

Why have physicians in general been slow to enthuse about geriatric practice? Certainly part of it is due to the fact that the physician needs maintain his self-esteem. Society acclaims the medical researcher who discovers something new and dramatic. The news media is full of descriptions of miracle drugs, heart surgery, etc., but few kudos go to the devoted physician who wrestles daily with chronic illnesses. There are few dramatic moments and only occasional gratitude expressed by patients with chronic illnesses. They read regularly about medicine's reported miracles and they are disappointed and angry with their own apparent lack of progress. To put it succinctly, physicians ordinarily do not like to take care of people who are slow to improve and who do take up much of their time. Also some believe that the doctor's own personal hang-ups might get in the way of his liking and seeking to serve old people.

"Actually we as physicians can never afford to forget how closely related are the phenomena of normal and pathological aging, how indistinct is their line of demarcation and how easily under the influence of a wide variety of factors one may be transformed into the other."[8]

*Memory and Intelligence.* One should not and cannot discuss old age without commenting upon two problems that are said to haunt the elderly. The first is the problem of memory; the second is that of intelligence. As far as memory is concerned, one does not have to await old age to have problems with that, but all is not lost, for there is a glimmer of hope in recent research. Contrary to the prevailing stereotype, the inevitability of memory decline with age as a clinical symptom is a complex phenomenon in older people which complaint must be differentiated from performance. Complaints can occur without an actual deficit in memory. Memory is, of course, impaired in organic brain disease, but not infrequently memory difficulties are associated with depression in which case the problem is reversible. I believe that much of the difficulty with memory is in recall: we get the name we strive to remember but our mental filing cabinets are quite full and some slowness is understandable.

As to intelligence and learning, it is believed that most old people can learn things as easily as they could when they were younger, although, obviously, many of them would not care to put these abilities to test in a television competition. Scientific studies also indicate that learning capacities do not slow with age. Were you to compare a group of seventy-year-olds with twenty-year-olds it might seem that there is a loss of intellectual functioning in the older group. But longitudinal studies—those which follow the same people over a long period of time—clearly show that intellectual abilities of healthy people grow greater through the years. While there are a number of modifiers which can influence how elderly persons react, for the "well aged" there is no marked impact on learning.

As to creativity and achievements, aging does not preclude them. The examples of outstanding achievements in the older age groups are many. In addition to those we see every day we recall that Michelangelo completed the dome of St. Peter's Cathedral at 70, Gladstone became Prime Minister of England at 84. Our own Chief Justice Holmes was productive and witty at 90. Handel, Hayden and Verdi completed their immortal works after the age of 70; Tintoretto painted an historic canvas at 90 and Kant did his philosophical masterpiece at 74. There are no time limits on creative work as long as illness does not supervene.

How then can the doctor teach people, and himself be taught to face the crisis of aging in a positive fashion? First, by accepting it as something positive not simply something to be endured. One must accept it as a new phase and a new life style and seek to discover the values and the precious opportunities available to make it worthwhile and fulfilling. The alternatives to this positive approach are not happy ones.

Growing old gracefully really requires a change of venue—the pressures—the push, the striving for recognition and advancement typical of earlier years can now be looked at with philosophical detachment and new perspective on life, love and the real meaning of existence be realized. This will bring with it a deeper insight and a true knowledge of the value of all things without the biases which earlier drove the person on. "Then young people can approach the older person without resentment since the elders have exchanged their throne of power for the seat of wisdom."[9] This wisdom cannot be learned from books nor can it be acquired in schools or universities. Only a lifelong process of gradual growth and maturing can bring this wisdom of the heart. The wise patience and calm of a mature person can be an encouragement, guide and stimulus for others.

Growing old in a positive way can make a person aware of how unstable and transient are so many things in life. Wealth and external achievements, beauty and health are fleeting and perishable. However, experiencing the instability is one thing; developing a new awareness of what is lasting and external is another; and this brings with it a new meaning and hope.

The person who has kept his mind active, curious, and thirsty for knowledge has the best chance of enjoying and being creative in his later years. It would be hard to think of Justice Holmes or Justice Brandeis as having been old men for they remained so dynamic. The older person who is able to interest himself in the arts and literature need never feel lonely or bored. He who can read and can cogitate will never think the world tedious.

Thus there is little justification for the physician to approach the emotionally distressed elderly patient with an attitude of hopelessness for often there are reversible components to their illnesses. Even in those individuals with obvious organic changes some facets of their personality shine through. Certain of their symptoms may be due to depression or even to a reversible acute confusional state. Some, in fact, may be due to other physical conditions such as cardiac, gastro-intestinal ills or some chronic deficiency. Sometimes their symptoms may be due to interaction of drugs presently being administered with those being taken for a longstanding condition.

The physician is well advised to suspect all drugs that the patient is taking for paradoxical reactions turn up in the elderly with unexpected regularity. Old people often react well to placebos but whether or not the active drug or placebo will be effectual will be due more to its symbolic significance and whether it represents the understanding concern and attention of the doctor who orders the substance. These concerns and attention are more potent than any drug in the pharmacopoeia.

To return to Neugarten's viewpoint, "The rewards in treating an older patient may therefore be very great. . . . In assisting older patients to come to peace with their lives and to master their narcissism, therapists may come to peace with their own lives and more quickly master their own narcissism." We have already learned from Nouwen that segregation and desolation are powerful alienating factors in the lives of the elderly, but the most destructive of all is self rejection. This ostracizes the elderly and strips them of the feeling of self worth. This is particularly true in the situation of those whose identity is lost in the past—in their previous jobs, and in "what might have been."

Finally the statement attributed to the famous Quaker philosopher E. Stanley Jones might be kept in mind:

> "The thing to do is neither to fear old age nor fight it but to accept it without tension and use it. When I say 'use it' I do not mean bear it or accommodate yourself to it, but take hold of it and make something of it. That is what nature does. She does not die drably, she puts on her most gorgeous robes in autumn, her yellows and her flaming reds and dies gloriously."

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# The Thyroid Nodule: Approach to Diagnosis and Therapy

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## Introduction

Thyroid nodules are one of the most challenging and perhaps controversial clinical entities in endocrinology. Opinions regarding the proper therapeutic approach to thyroid nodules are so diverse, that some authorities advocate surgically removing virtually all thyroid nodules, whereas others advocate following the majority of patients with thyroid nodules medically. Recent data linking thyroid malignancy with head and neck irradiation has enhanced public and professional awareness of nodular thyroid disease and as a result the clinician will be called upon with increasing frequency to evaluate this condition. It is the purpose of this review to outline the incidence of nodular thyroid disease and thyroid malignancy, the risk factors for malignancy in nodular goiters, and the methods for distinguishing benign from malignant nodules. Based on this information, a rational approach to the diagnosis and therapy of thyroid nodules will be presented.

## Incidence of Thyroid Nodules and Malignancy

The controversy regarding therapy for thyroid nodules has partially arisen from two major unanswered questions: what is the true incidence of thyroid nodules in an unselected population? and what percentage of these are malignant? Two types of studies have attempted to answer these questions. The first concerns autopsy series in which glands are carefully sliced and examined histologically. The second involves clinical studies in which thyroid glands are palpated in a large population of normal subjects (without known disease), and detected nodules are either surgically removed or followed medically.

### Autopsy Series

Mortensen, et al, examined the thyroid glands of 1000 subjects without known thyroid disease who underwent post mortem exam.[1] By careful sectioning of the thyroid a 49.5% incidence of single or multiple nodules was noted, although less than one-half of these were detected by direct palpation of the gland. The incidence of nodules was 10-20% higher in females than males, and the frequency increased with advancing age in both sexes. Primary occult carcinoma was observed in 4% of these nodular glands. In contrast; Schlesinger and co-workers noted only an 8% incidence of thyroid nodules at autopsy, however, they included only nodules ( > 1 cm in diameter) which they felt would be clinically palpable.[2] They also noted an incidence of malignancy of 4-5% in glands in which a single nodule was present. Similarly, Hull[3] noted a 12% incidence of palpable nodules, and a 5% incidence of cancer in these nodular goiters. Thus autopsy data suggest an incidence of nodular thyroid disease which approaches 50% in the general population, but a much lower frequency of occurrence (8-12%) if only potentially palpable nodules are considered. In the latter, between 4-5% may contain occult thyroid cancer.

### Clinical Series

Perhaps the largest clinical series dealing with the incidence of thyroid nodules in unselected patients is the study of Vander, et al which involved 5000 normal subjects (aged 30-59) from the city of Framingham, Mass.[4] They noted a 4% incidence of nodular goiters by palpation (3% were uninodular and 1% multinodular). To assess what proportion of these nodular goiters might develop into clinically significant thyroid cancer, 199 subjects were followed for up to 15 yrs.[5] Nodules remained unchanged in 148 patients and 45 subjects had their nodules excised; among these all were found to be benign. Fifteen subjects died from other causes, but none had thyroid cancer. While this study indicates that no patient with a clinically benign

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nodule showed evidence of thyroid malignancy during a 15 yr. period of close observation, the results must be viewed with caution. Not only is the sample size relatively small, but it is unknown how many of the thyroid nodules which were surgically removed might have developed into thyroid cancer. Furthermore, it might take longer than 15 years for well differentiated thyroid cancers to become manifest.

Miller reported an 11.2% incidence of nodular thyroid disease in a female adult hospital and clinic population, and estimated an 8% incidence in both sexes.[6] Of 435 thyroidectomies performed on these patients with clinically benign nodular goiters, 3.7% were found to contain cancer. All patients with a definite preoperative diagnosis of thyroid cancer, or who presented with metastatic disease were excluded. Thus, based on these clinical studies, the incidence of nodular goiter in unselected populations is approximately 4-8%, values not dissimilar to those observed in autopsy series. Probably a small percentage of these nodular goiters contain cancer. (Table 1)

Table 1

INCIDENCE OF THYROID NODULES

1. 4-8% of population have palpable thyroid nodules
2. Of these, 4-5% are malignant

### Surgical Series

Surgical series generally show a much higher incidence of thyroid cancer in nodular thyroid glands. This has been attributed to selection of patients with a high risk of malignant disease. Many surgical studies fail to eliminate those with obvious thyroid malignancy, or those who present with metastatic disease. Figures for the incidence of cancer in surgically treated uninodular goiter average between 9 and 33%, and for multinodular goiter between 3-10%[7]. If one extrapolates these data to the general population with thyroid nodules, one would expect an extremely high rate of thyroid cancer which is not substantiated by tumor registry statistics. Only 1000 deaths per year in the U.S. result from thyroid cancer[8]. Moreover, it has been estimated that if all thyroid nodules were removed surgically, a minimum of 1 patient per 1000 (some of whom never had malignancy) would succumb to operative complications.[9]

## Risk Factors for Malignancy

Endocrinologists have become quite adept at selecting out those patients whose thyroid nodules are most likely to be malignant. Using the history, physical exam, and various laboratory aids, one can predict malignancy with a reasonable degree of accuracy. Clinical features suggestive of malignancy are summarized in Table 2.

Table 2

FEATURES SUGGESTIVE OF MALIGNANCY

| *History* | *Physical Exam* |
|---|---|
| 1. Young Age | 1. Hardness |
| 2. Male Sex | 2. Fixation |
| 3. Prior Head and Neck Irradiation | 3. Single Nodule |
| 4. Family History of Medullary CA | 4. Local Lymph Node Enlargement |
| 5. Hoarseness | |
| 6. Dysphagia | |
| 7. Dyspnea | |
| 8. Recent Growth | |
| 9. Pain | |

### History

**Age:** The patient's age can be a valuable predictor of malignancy in thyroid nodules. Most studies indicate that nonmalignant nodules are very rare before puberty, but after this time, they steadily increase in frequency throughout life. Although thyroid cancer is also uncommon before puberty, it constitutes the most frequent pathologic change in nodular goiters in this age group.[10] It has been estimated that between 30 and 50% of thyroid nodules in children are malignant.[11] In general, the chance that a given thyroid nodule will be malignant decreases as age increases.

**Sex:** It has been widely accepted that males exhibit an increased frequency of malignant thyroid nodules. This has been partially based on indirect evidence indicating that the female:male ratio for thyroid nodule is 4-5/1, while the female:male ratio for thyroid cancer is 2/1.[12] In addition, most surgical series show that a higher percentage of males referred for thyroid surgery prove to have thyroid cancer. At particular risk for thyroid malignancy is the young male with a thyroid nodule. It has been estimated that 70% of such nodules are malignant.

**Symptons:** Complaints of pain, dysphagia, hoarseness, and dyspnea in patients with thyroid nodules are all warning signals for the presence of thyroid malignancy. The rapid appearance of a thyroid nodule or change in size of a previous nodule also suggests thyroid cancer, but a similar growth pattern associated with neck pain is also characteristic of hemorrhage into a benign nodule. The series of Bowens and Vander[13] lends support to the usefulness of symptoms as a predictor of malignancy. They divided patients with nodular goiter into symptomatic and asymptomatic groups prior to surgery. Ninety-five percent of the thyroid nodules found to be malignant occurred in the group who had symptoms referable to their thyroid. Unfortunately, many of the above mentioned symptoms are more often suggestive of aggressive thyroid malignancies such as anaplastic, follicular, medullary or far advanced papillary carcinoma which are not usually amenable to surgical treatment.

### Physical Examination

Several studies have demonstrated the predictive value of the physical exam in the clinical differentiation of malignant thyroid nodules. Physical findings suggestive of thyroid carcinoma include hardness, adherence to adjacent structures, tracheal deviation, and the presence of enlarged cervical lymph nodes.[13] [14] Shimooka classified a group of 200 patients with thyroid nodules based on physical exam and history into a group with "probable benign nodules", a group with "suspected cancer", and a group with "probable cancer."[14] Of 200 patients classified as having benign nodules, 2% were found to have thyroid cancer. In contrast, 28% of those with suspected cancer and 53% with probable cancer were found to have malignant nodules at surgery.

Another helpful physical finding which lessens the chance of malignancy is the presence of multinodular goiter. Most experts agree that cancer is more frequent in uninodular than in multinodular goiter, however, few studies have directly addressed this issue. In Mazziferri's series of 576 patients with papillary cancer, only 3.5% were found in clinically multinodular glands while 71% were found in uninodular glands[2]. An exception to the generalization that multinodularity lessens the likelihood of thyroid cancer is the presence of multinodular goiter in children. Such thyroid glands have a high probability of being malignant and should be surgically removed. A further word of caution is warranted regarding multinodular thyroid glands. Since thyroid cancer may occur in these goiters, the presence of multinodularity should not preclude surgical excision if other features in the physical exam and history are suggestive of thyroid cancer.

### Family History

A positive family history for thyroid carcinoma in a patient with a thyroid nodule should raise the possibility of medullary carcinoma of the thyroid, and a fasting plasma calcitonin should be obtained. Although the majority of these tumors are sporadic, 5% are familial and are inherited as an autosomal dominant trait. It is probably not cost effective to screen all patients having nodular goiters with a plasma calcitonin measurement, since the expected frequency of an elevated plasma calcitonin in an unselected population with nodular goiters is extremely low[15].

### Past History of Head and Neck Irradiation

The problem of radiation related thyroid cancer was reemphasized in 1976 by two major studies from Chicago.[16] [17] These studies showed a strong correlation between head and neck irradiation in childhood and thyroid nodules and cancer. Approximately 27% of patients with a history of childhood head and neck irradiation were found to have thyroid nodules by palpation or thyroid scan. Of those with thyroid nodules, 30-40% were found to have malignant nodules at surgery. Most of these cancers were papillary or papillary-follicular, with a high incidence of multifocal disease. Unlike non-radiation associated cancer in which there is a striking predominance of females, there was an equal tumor incidence between men and women. These and other studies have revealed a direct correlation of tumor incidence and radiation dose, even with very low radiation doses. The average latency from exposure to diagnosis is approximately 20 years. Finally, there is no evidence that radiation related thyroid cancer is more aggressive or life threatening than non-radiation associated cancer.

Despite multiple conferences on this topic, the proper approach to radiation related thyroid nodules is controversial. The majority of endocrinologists feel that all patients with a palpable thyroid nodule and a history of head and neck irradiation should have surgery. Most favor total or near total thyroidectomy because of the high incidence of multifocal disease. In addition, some would operate on all patients with a definite localized cold area by thyroid scan despite a normal gland to palpation.[18] Others place these patients on thyroid hormone therapy in an attempt to unmask any nodules with shrinkage of the normal thyroid tissue. All experts agree that patients with a normal gland to palpation and a normal scan should be examined yearly for the development of thyroid nodules. Whether thyroid hormone prophylaxis decreases the likelihood of a patient's developing thyroid cancer is unknown.

## Diagnostic Tools for Distinguishing Benign from Malignant Nodules

### Thyroid Scan

The thyroid scan serves two useful purposes. It identifies the functional characteristic of a thyroid nodule, and it identifies the presence of other nodules in a clinically uninodular gland. The main value in determining the functional status of a nodule is to specifically identify those that are hyperfunctional. Multiple clinical series have established the rarity of thyroid cancer in hyperfunctioning or "hot" nodules. The documentation of a functioning or hypofunctioning nodule is of limited diagnostic value. Kendall, et al, demonstrated that the majority of both benign and malignant nodules were "cold" by thyroid scan but that a substantial proportion of both types of nodules were functioning or "warm"[20]. Nelson, et al, recently underscored the limited value of thyroid scans as a predictor of malignancy by correlating the scan findings with the surgically documented location and histology of thyroid cancer[21]. They found that 24% had a palpable nodule at the site of the malignancy which was not noted by thyroid scan, and that 16% had both a normal clinical exam and thyroid scan in the area of the malignancy with a palpable, benign lesion in another part of the thyroid.

Whether identifying the presence of other nodules by scan in a clinically uninodular gland is of diagnostic usefulness is controversial. Many experts believe that presence of multiple nodules reduces the risk of malignancy. On the other hand, several studies suggest that there is no significant difference in the incidence of carcinoma in uninodular or multinodular glands as documented by scan (rather than palpation)[27 28]. Despite the above limitations (Table 3), a thyroid scan should be obtained in all patients with a thyroid nodule, particularly for identifying those nodules that are hyperfunctioning and for identifying the presence of multiple nodules. However, the presence of hyperfunctioning nodule or multiple nodules should not preclude surgery if a nodule is judged to be malignant by other criteria.

Table 3

LIMITATIONS OF THE THYROID SCAN

1. Normal scan does not rule out malignancy
2. Provides no data regarding whether cold nodule is malignant or benign
3. Identification of a functioning or multiple nodules does not exclude malignancy

**Ultrasonography**

Thyroid ultrasonography has recently been proposed as a means for differentiating benign from malignant nodules. Its principal use has been in distinguishing cystic from solid nodules, which it accomplishes with a high degree of accuracy. Miskin et al correctly diagnosed 49 of 50 solitary hypofunctioning nodules as cystic or solid using preoperative ultrasonography.[24] The importance of establishing the presence of a purely cystic nodule lies in the fact that malignancy is rare in such lesions.[25] Another value in identifying the presence of a cyst is that such lesions can easily be aspirated and the fluid sent for cytological examination. However, thyroid ultrasonography has been of no benefit in differentiating solid benign from solid malignant nodules, or in predicting the chance of malignancy in a partially solid, partially cystic lesion[24].

**Needle Biopsy**

*Large Bone Needle Biopsy:* Needle biopsy of thyroid nodules has largely been restricted to certain centers where medical specialists or surgeons have become skilled with this technique.[26] Its popularity has been limited because of fear of trachael puncture, hemorrhage, and recurrent laryngeal nerve damage and the theoretical risk of implantation of malignant cells along the needle track. It has been reported that a correct diagnosis can be established in 90% of patients, and that the risk of complications is extremely low. Thus, in certain hands, needle biopsy can be a safe, accurate outpatient procedure for patients who are high risk surgical candidates.

*Fine Needle Aspiration:* Although this technique has been extensively used in Scandinavia for over 10 years, it has only recently been applied to the diagnosis of thyroid nodules in the United States. The technique involves the insertion of a size 21-27 gauge needle into a thyroid nodule and applying strong suction to an attached syringe. The aspirate is immediately smeared on a glass slide, fixed, and stained by the Papanicolaou method. The slide is then examined by a cytopathologist. A similar technique can be applied to cystic lesions, but a larger needle, size 18-21, is usually necessary. Recent studies have demonstrated that adequate cytological material can be obtained in 92-97% of cases.[27] The incidence of false positive diagnoses for carcinoma appears to be very low (0-6%); however, the true incidence of false negative diagnoses for carcinoma is unknown since many nodules have not been removed based on a benign diagnosis using this technique. There have been no reported complications, including spread of cancer cells along the needle track. Widespread use has thus far been limited by the unknown incidence of false negative aspirates and the dearth of cytopathologists skilled in interpreting such specimens. It is likely, however, that this technique will be used more extensively in future.

**Response to Thyroid Hormone Therapy**

Regression of nodules after thyroid hormone therapy has been commonly used as an indication of a benign lesion. This approach is based on the theory that most benign thyroid nodules have resulted from repeated cycles of TSH stimulation, resulting in hypertrophy and/or adenomatous changes. Adequate doses of exogenous thyroid hormone suppresses TSH secretion, thus preventing further growth of thyroid nodules and allowing possible regression. Astwood, et al, demonstrated that as many as 46% of patients with single nodules and 24% of patients with multiple nodules had moderate or complete regression of nodules following a course of thyroid hormone therapy.[28] Based on this response, he considered that these nodules were benign. On the other hand, many well differentiated thyroid cancers have also been shown to be partially TSH dependent and thus would also be expected to decrease in size with thyroid hormone treatment. In patients with papillary carcinoma, 13% given thyroid hormone preoperatively showed partial (but not complete) shrinkage of their thyroid nodules.[12] Thus, complete regression of a thyroid nodule is strong evidence for a benign lesion, but partial regression on thyroid treatment does not exclude an underlying malignancy. Despite the limitations of thyroid hormone therapy in differentiating benign from malignant nodules, this method has commonly been employed as a first approach to the evaluation of thyroid nodules in patients without other risk factors for thyroid malignancy, or without contraindications for the use of thyroid hormone.

### Natural History of Thyroid Cancer

Physicians should be aware of the natural history of thyroid cancer before formulating an approach to thyroid nodules. The malignancy most likely to be found in a population of patients with thyroid nodules is of the papillary type. This tumor comprises approximately 60-80% of all thyroid cancer, but is responsible for a very small percentage of the deaths from thyroid cancer. In Mazzaferri's series of 576 patients with papillary carcinoma, only 5 patients died of papillary cancer during an average 7 year follow up.[12] Regardless of the type of surgical therapy, cumulative survival at 5 and 10 years was 97.8% and 94.9% respectively, which is not significantly different from that calculated for a normal population of comparable age, sex, and race. In the small percentage with metastatic disease, survival for years, and even decades was not uncommon. Of note is the observation that the time lapsing from discovery of the primary lesion to surgery did not influence recurrence or survival. Seventy percent of the tumors in this series were either occult, defined as less than 1.5 cm in diameter, or intrathyroidal, defined as greater than 1.5 cm but without capsular invasion. A similar percentage of occult and intrathyroidal tumors was found in Woolner's series of 541 cases of papillary cancer.[29] Survival figures from this series following various forms of surgery revealed a 10 year survival of 90% and 84% for occult and intrathyroidal cancer respectively. Thus, most cancerous thyroid nodules are papillary, and the majority of these are either occult or intrathyroidal, the group with the best prognosis.

Follicular carcinoma comprises about 15-20% of cancerous thyroid nodules. These tumors have an excellent prognosis if capsular or vascular invasion have not occurred at the time of resection. In a long-term follow-up study from the Mayo Clinic, only 3 of 104 patients with noninvasive follicular carcinoma died of their tumor.[29] However, 10 and 20 year survival figures for invasive disease were 34% and 16% respectively. Similarly, medullary carcinoma of the thyroid (which comprises 5% of thyroid cancers) has an excellent prognosis if metastatic disease has not occurred at the time of resection. Woolner reported a survival rate comparable to the normal population in individuals without metastatic disease.[30] However, in the patient with metastatic disease at presentation, 5-year survival was reduced to 40%. Anaplastic thyroid cancer, comprising 10% of all thyroid cancers, is almost universally lethal, despite any form of therapy (including surgery). The 5 year survival for this tumor is approximately 20%.

In view of the relative infrequency of thyroid cancer in thyroid nodules, and the indolent and often nonlethal nature of the tumors comprising the majority of these cancers, an aggressive surgical approach to all thyroid nodules is probably not warranted. This is especially true in the elderly who are more likely to die of other causes, despite the presence of a well differentiated thyroid cancer. On the other hand, the early surgical approach should not be entirely dismissed, since such intervention may effect a cure in a potentially metastatic tumor (particularly follicular carcinoma).

### Approach to Thyroid Nodules

Knowing the risk factors for thyroid carcinoma and utilizing the diagnostic tools just described, one can formulate a rational approach to thyroid nodules. The initial work up should include thyroid function tests, thyroid antibodies, thyroid scan, and a chest x-ray (Table 4). These basic tests quickly identify the presence of Hashimoto's thyroiditis, a hyperfunctioning nodule, a multinodular goiter and an aggressive malignant tumor which has already metastasized to the lung. Those patients with a toxic multinodular goiter and a nodule which is clinically suspicious for cancer should receive surgery as both a therapeutic and diagnostic modality. Euthyroid patients with multinodular goiters, who are young (>20 years), who have a history of head and neck irradiation, or whose goiter contains a nodule suspicious for carcinoma should be considered immediate surgical candidates. All others with multinodular goiters may be followed clinically, either with or without thyroid hormone therapy. If such patients develop symptoms or signs suggestive of carcinoma, surgery is indicated (Table 5).

Table 4

INITIAL LABORATORY EVALUATION OF THYROID NODULES

1. Thyroid function tests
2. Thyroid scan
3. Thyroid antibodies
4. Chest x-ray

Table 5

APPROACH TO MULTINODULAR GOITER BASED ON THYROID FUNCTION TESTS

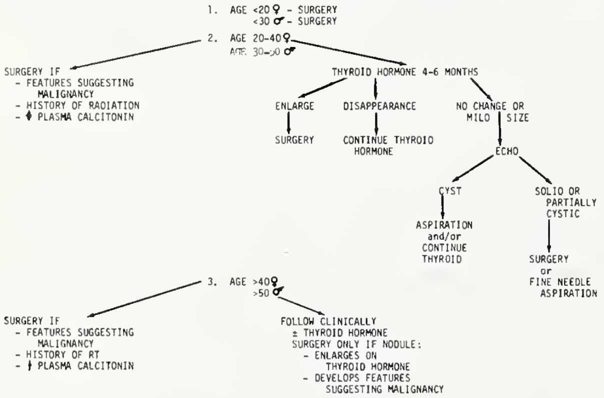
1. Hyperthyroid
   Treat hyperthyroidism medically or surgically
2. Hypothyroid
   Treat with thyroid replacement
3. Euthyroid
   Surgery if one or more of the following
   1. Age < 20 years
   2. History of neck irradiation
   3. Elevated calcitonin
   4. Clinical features of malignancy

   Otherwise, thyroid hormone treatment or follow clinically

Patients with solitary nodules which are cold or not hyperfunctioning can be approached in the following manner (Table 6). All patients (despite age or sex) with symptoms or signs suggestive of carcinoma, with a history of head and neck irradiation, or with an elevated plasma calcitonin should be considered surgical candidates, All females less than age 20 and all males less than age 30 should also be considered surgical candidates because of the great risk of carcinoma in these age groups. Females between age 20 and 40 and males between age 30 and 50 can be given a 4-6 month trial of thyroid hormone therapy. If the nodule completely regresses, the patient should be continued on thyroid hormone. If the nodule enlarges, the patient is considered a surgical candidate. If there is no change or a partial regression in size, a thyroid echo can be obtained to identify those with purely cystic lesions. These patients can be continued on thyroid hormone therapy and/or have their cysts aspirated and the fluid sent for cytological exam. If the echo reveals a solid or mixed solid and cystic nodule, these patients should be considered for surgery or fine needle aspiration (if cytological expertise is available). Females greater than age 40 and males greater than age 50 can be followed clinically with or without thyroid hormone therapy. Patients older than age 65 or with cardiac disease are best followed without thyroid hormone therapy. If the patient develops clinical features suggestive of carcinoma, including enlargement, on thyroid hormone, they are considered surgical candidates.

Table 6

APPROACH TO SOLITARY THYROID NODULES BASED ON AGE


1. AGE <20 ♀ - SURGERY
<30 ♂ - SURGERY
2. AGE 20-40 ♀
AGE 30-50 ♂
SURGERY IF
- FEATURES SUGGESTING MALIGNANCY
- HISTORY OF RADIATION
- ↑ PLASMA CALCITONIN
THYROID HORMONE 4-6 MONTHS
ENLARGE
SURGERY
DISAPPEARANCE
CONTINUE THYROID HORMONE
NO CHANGE OR MILD ↓ SIZE
ECHO
CYST
ASPIRATION and/or CONTINUE THYROID
SOLID OR PARTIALLY CYSTIC
SURGERY or FINE NEEDLE ASPIRATION
3. AGE >40 ♀
>50 ♂
SURGERY IF
- FEATURES SUGGESTING MALIGNANCY
- HISTORY OF RT
- ↑ PLASMA CALCITONIN
FOLLOW CLINICALLY
± THYROID HORMONE
SURGERY ONLY IF NODULE:
- ENLARGES ON THYROID HORMONE
- DEVELOPS FEATURES SUGGESTING MALIGNANCY

Other factors which need to be considered before a patient is referred for surgery are the skill of the surgeons at the institution, and the presence of other medical problems which might increase the risk of surgery. These factors are particularly important in view of the frequency of benign nodules, the relative rarity of thyroid malignancies, and the often benign, protracted course of most thyroid cancers. Another factor which should influence the decision for surgery is the patient's concern about cancer. A patient who is burdened with the worry of thyroid cancer despite adequate physician counseling, should be considered a surgical candidate.

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# Nutritional Support of Burn Patients: Bridgeport Hospital Burn Unit

WALTER E. PLEBAN, M.D.

**ABSTRACT—The nutritional support of the burned individual has become a priority at the Bridgeport Hospital Burn Unit. The severely burned patient is supported by enteral feedings via well-tolerated silastic number eight size feeding tubes. A nutritional management record sheet is prepared and evaluated with the aid of the clinical dietician, and the nutritional profile is frequently reassessed. An interested and dedicated nursing and house staff help to review and assess nutritional needs. The chance of survival of the burned victim is greatly enhanced by these principles and action.**

The treatment of major body burns has improved vastly over the past decade due to many factors, especially with the expanded interest and knowledge of improved nutritional support. A better understanding of the hypermetabolic response and the marked metabolic needs of the severely burned individual has focused attention on the necessity of adequate nutritional needs.

We now know that there is a resetting of the central nervous system temperature control center, and as a result, the critical temperature is increased slightly. The burn patient has an elevated core temperature and remains internally warm, thus slightly febrile (38 degrees Centigrade).

The burned patient has severe metabolic expenditure with stimulated neurohormonal control mechanisms. In moderate to severe burns, energy requirements of 5000 calories a day may be present. Weight loss following the burn injury was formerly considered to be inevitable. Many patients would survive the initial burn trauma, would be successfully resuscitated with fluids, would endure one to two months of debridements and grafting procedures, but would eventually succumb to infection, and to concomitant starvation. We now know that an acute loss of 10 percent of the pre-burn weight is associated with numerous and severe complications. These are primarily poor wound healing and decreased immunological responses. Once the acute weight loss exceeds 30 percent of the pre-burn levels, death will follow.

The burn team at the Bridgeport Hospital is aware

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of the tremendous catabolism in the treatment of the burned patient, and particular attention is placed to the nutritional needs. The initial fluid resuscitation in the acutely injured individual is of no practical significance in providing caloric needs. Once the initial gastric ileus has cleared, usually by the fourth or fifth day, initial nutritional support is provided by nasogastric silastic feeding tube (Keofeed). Elemental diets are infused via a size eight silastic tube, with the aid of an infusion pump. In burns of less than 40 percent magnitude, most patients can be adequately fed with a high protein, high caloric diet, and do well on the 3000 to 3500 caloric diet offered.

The patient admitted with 40 percent or greater burns, is considered to be in danger due to the increased metabolism needs. Admission weight is recorded, and a metabolic scale is available for daily weighing. There is usually weight gain due to burn edema and water retention over the first 5 to 6 days, and then a marked weight loss in the next two weeks. Once burn edema has cleared, one quickly notes the ravages of accelerated metabolism. Members of the Bridgeport Hospital Burn Unit utilize the Curreri Formula in the determination of daily caloric requirements. In adult patients with burns greater than 20 percent of body surface area, the following formula, as proposed by P. William Curreri, is used: 25 Kcal x Kg of body weight + 40 Kcal x percent of burn, equals proposed caloric needs. The maintenance requirements of children are higher and the formula is revised to 60 Kcal x Kg body weight + 35 Kcal x percent of burn, equals proposed Kcal needs. The above is incorporated into a Nutritional Management record sheet, which becomes an integral part of the patient's chart. The registered dietician is instrumental in the patient's nutritional evaluation and assessment. The physician works with the dietician in writing the proper nutritional orders to help the patient meet his caloric and protein requirements.

Enteral feedings are not without complications, and great care and attention must be provided in their utilization. These solutions are hyperosmolar, and must be administered specifically and patiently. Typically a half strength solution of the commercially prepared diet (Vivonex HN) is used at 50-60 ml per hour. The day following the rate is increased to about 100 ml per hour. If well tolerated the concentration is then increased to full strength, 50-60 ml per hour, and then increased gradually and steadily to a maximum of 125 ml per hour. This will allow for infusion of approximately 4000 calories per 24 hours.

Additional feeding may be accomplished with the peripheral administration of Intralipid, an intravenous fat soybean emulsion. The average adult would receive 500 ml to 1000 ml a day, with one ml having the equivalent of one Kcal. Intravenous hyperalimentation (TPN), is infrequently utilized in major burn victims due to the higher risk of sepsis in association with central vein catheter contamination. However, the Burn Team at the Bridgeport Hospital has on occasion been forced to use both enteral feedings and central line intravenous feeding in combination, in the 70-90 percent burn victim. These individuals are usually septic and unfortunately both modalities cannot be supported over a prolonged period of time.

Improved nutritional methods, and greater understanding of metabolic needs and requirements in the severely burned individual, have increased survival in these individuals. An interested supporting staff (nursing, dietary), and the presence of an interested house staff and attending staff, form the nucleus of the burn team in implementing nutritional standards in the care of the severely burned individual.

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# Tonsils and Adenoids: A Surgical Dilemma

DOUGLAS MANN, M.D., CLARENCE T. SASAKI, M.D.
AND HAROLD R. PILLSBURY, III, M.D.

**ABSTRACT—Controversy over T&A surgery continues without satisfactory resolution. However, our current inability to resolve conflicting opinions need not result in total condemnation of adenotonsillectomy in general. Indications for T&A surgery are discussed from a conservative point of view consistent with the perspective shared by the University staff in otolaryngology at the Yale School of Medicine.**

In the year 1979, there remain many unanswered questions concerning the role of tonsillectomy and adenoidectomy in the management of ear, nose, and throat disease. Inadequate definition of disease processes and faulty documentation of treatment results have posed a serious dilemma for the otolaryngologist who must now justify his surgery. In order to avoid condemning T&A surgery altogether, we present the pertinent evidence in favor of adenotonsillectomy. It will become obvious that tonsillectomy and adenoidectomy, although frequently done together, are separate operations with separate indications.

### Absolute Indications for Adenotonsillectomy

1. *Acute Airway Obstruction.* Acute airway obstruction may occur as a result of hypertrophied tonsils and adenoids, most often associated with infectious mononucleosis in our experience. Urgent adenotonsillectomy may be life-saving, if obstructing tonsils and adenoids fail to respond to steroids.

2. *Sleep Apnea Syndrome.* The hypersomnia sleep apnea syndrome is characterized by apneic episodes which may repeatedly wake the patient from sleep, resulting in an irritable, sleep-deprived individual. Among hypersomneic patients, fatalities due to industrial and automotive accidents are common, and hypoxia-induced cardiac arrhythmias during sleep pose an additional serious threat.[1] Removal of obstructing tonsils and adenoids may prove life-saving in this very select group of patients.

3. *Cor Pulmonale.* In a subgroup of children with T&A hypertrophy, pulmonary hypertension and right heart failure may develop. These conditions are reversible within 24 hours of tonsillectomy and adenoidectomy. Chronic hypercapneia and hypoxia are believed to be the mechanism of this abnormality, a condition which is cured by relieving the airway obstruction.[2]

### Indications for Tonsillectomy

1. *Peritonsillar Abscess.* Peritonsillar abscesses tend to recur after mere incision and drainage. In the recent literature, tonsillectomy has been advocated in the acute stage of abscess,[3 4] but it has been our practice to proceed with surgery after infection has subsided. Generally, tonsillectomy is performed 3 to 4 weeks after drainage of the abscess, in order to minimize general anesthetic risks and excessive bleeding, but yet to avoid difficult dissection through scar tissue.

2. *Chronic Tonsillitis in Adults.* Tonsillectomy for chronic tonsillitis is still a common operation. Mounting public interest in the cost-benefit ratio of medical care has produced a need to re-evaluate our concept of chronic tonsillar infection. Does chronic tonsillitis, in fact, exist at all? And, if so, can its diagnosis be supported etiologically?

Sasaki and Koss[5] studied quantitative bacterial counts of tonsil tissue obtained from 2 groups of adult

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patients (age 18-36). All tonsils from 29 patients revealed normal flora by routine culture techniques. However, the mean bacterial counts in symptomatic patients (20) revealed significantly higher levels ($2.6 \times 10^6$ per gm of tonsil tissue) than did those in a control group of patients ($7.8 \times 10^3$). This control group consisted of 9 patients undergoing tonsillectomy during removal of second branchial cleft cysts. High bacterial levels correlated well with historical evidence of sore throat (greater than 7 per year) and with the presence of dependent nodal hypertrophy (palpable jugulodigastric lymph nodes). High bacterial levels correlated inversely with the number of tonsillar crypts and with actual tonsil size. In tonsils with high levels of bacteria, fewer crypts due to scarring were visible. Furthermore, tonsils chronically infected tended to weigh less than normal unscarred tonsils. Interestingly, preoperative estimation of tonsil size correlated poorly with actual size weight, Because tonsils may be exophytic or embedded, preoperative visual estimation of size was believed to be of little value. Tonsil enlargement need not signify chronic infection.

This study produced the first substantiated evidence of chronic bacterial infection in tonsils of adult patients and helps, therefore, to select those patients who might optimally benefit from tonsillectomy. Indications for elective tonsillectomy in patients over age 18, therefore, include (1) greater than 7 episodes of sore throat per year; (2) palpable jugulodigastric nodes; and (3) fewer than 5 visible crypts per tonsil.

3. *Chronic Tonsillitis in Children.* Chronic tonsillitis, characterized by greater than $10^5$ bacteria per gm of tonsil tissue, is now readily identifiable in adult patients by virtue of irreversible, end-stage signs and symptoms. However, to date, similar criteria in children are lacking. It is therefore extremely difficult to identify those children who will develop chronic tonsillitis before the occurrence of irreversible signs and symptoms later in life.

If chronic tonsillitis in childhood remains undefined, is tonsillectomy a justifiable procedure? Furthermore, does tonsillectomy in children adversely affect immunologic reserves? The data fail to support measurable immunodeficiency from tonsillectomy. Kerr[6] studied 96 children with recurrent sore throats in whom he found no differences in serum IgG, IgA, or IgM levels as compared to age-matched healthy control patients. Furthermore, no change in immunoglobulin levels could be identified after tonsillectomy was performed.

McKee[7] prospectively studied 400 children in Great Britain. Children with more than 2 sore throats per year and enlarged cervical lymph nodes were divided into 2 groups. One group underwent tonsillectomy. The other was observed for 2 years. Patients treated expectantly developed 11.43 sore throat days per year, as opposed to 1.10 sore throat days per year in operated patients. Similar studies by Roydhouse[8] in New Zealand and Mawson[9] in Great Britain confirmed these findings.

Although it appears that tonsillectomy in childhood may be beneficial, it is not yet precisely known which patients will benefit optimally from its use. Criteria for tonsillectomy in childhood have yet to be defined in a precise manner. Such determinations, currently being conducted at the University of Pittsburgh,[10] promise to clarify our point of view and thereby sharpen treatment policies on this controversial medical and economic issue.

Until guidelines for tonsillectomy in children are established, the following criteria currently represent indications for tonsil removal at the Yale-New Haven Hospital: (1) greater than 3 episodes of sore throat per year, each episode verified as tonsillitis by a pediatrician or an otolaryngologist—such verification, we believe, is important in a large teaching hospital; and (2) palpable jugulodigastric lymph nodes.

### Indications for Adenoidectomy

1. *Serous otitis media.* Serous otitis media is characterized by middle ear effusion, consisting of a sterile pale-yellow transudate. Because of the proximity of the adenoids to the eustachian tubes, it seems reasonable to expect that adenoid infection or hypertrophy could adversely affect middle ear ventilation through the eustachian tubes. Eustachian tube obstruction leads to negative middle ear pressure, resulting in serum transudation. When air, which is ordinarily absorbed by the respiratory mucosa of the middle ear, cannot be replenished, the tympanic membrane will retract against an air-fluid level. This is not a serious abnormality, *per se,* unless bacteriologic infection results by organisms normally inhabiting the nasopharynx.

If decongestants fail to clear middle ear effusion within 6-8 weeks, it is our practice to ventilate these middle ears through a myringotomy and perform adenoidectomy to improve eustachian tube function. Bluestone[11] demonstrated that adenoidectomy was more likely to benefit children with X-ray evidence of eustachian tube obstruction and/or large adenoids. Children with small adenoids and/or nasal allergy tended to have recurrent disease within 9 months of operation. In these children, tympanostomy tubes are recommended in conjunction with adenoidectomy.

### Discussion

Tonsillectomy and adenoidectomy are no longer considered surgical procedures possessing mystical attributes. As heightened understanding of upper respiratory pathophysiology is acquired, guidelines have emerged which dictate a more precise use of 2 surgical procedures now known to produce widely differing effects. Although tonsillectomy and adenoidectomy together play a major role in overcoming certain types of upper airway obstruction, tonsillectomy alone may benefit the patient with chronic tonsillitis suffering from recurrent sore throat, malaise, and fever. Adenoidectomy alone may be used successfully in the treatment of chronic middle ear effusions and deafness.

A tempered approach, employing controlled prospective investigation, has now replaced initial widespread opposition to adenotonsillectomy. Lest the potential benefits of T&A surgery go unrecognized, we look forward to the results of such investigations in the hope of further improving patient care.

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# Pulmonary Embolus Complicating Clavicle Fracture

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**ABSTRACT—A non-fatal pulmonary embolus was documented in a young man following clavicular fracture. Thrombosis of the subclavian vein was demonstrated by venogram. Aggressive diagnostic measures followed by systemic anticoagulation are recommended in this life-threatening situation. Recommendations for or against open reduction of the clavicle should be governed by standard orthopedic criteria. Treatment should be directed to alleviating compression and minimizing the risk of pulmonary embolus.**

Complications of fractures of the clavicle, especially of the middle third, are usually either neural or vascular; and both immediate and late vascular complications are well recognized. Pulmonary embolus, however, is a rare complication of this injury[1] and has not been thoroughly documented in the past.

### Case Report

A healthy 22-year-old male was involved in a motorcycle accident, sustaining a displaced comminuted fracture of the right clavicle as his only significant injury. Two days after admission to the hospital, open reduction and internal fixation of this fracture was carried out under general anesthesia.

On the second post-operative day, the patient complained of sudden pleuritic right sided chest pain. Arterial blood gases were determined disclosing a PH of 7.47, PCO2 of 43 torr, and a PO2 of 69 torr. An electrocardiogram was normal as was a chest x-ray, but a radioisotope lung scan demonstrated a perfusion defect in the right lower lobe. (Fig. 1) Treatment with intermittent intravenous Heparin was initiated, and a venogram was performed demonstrat-

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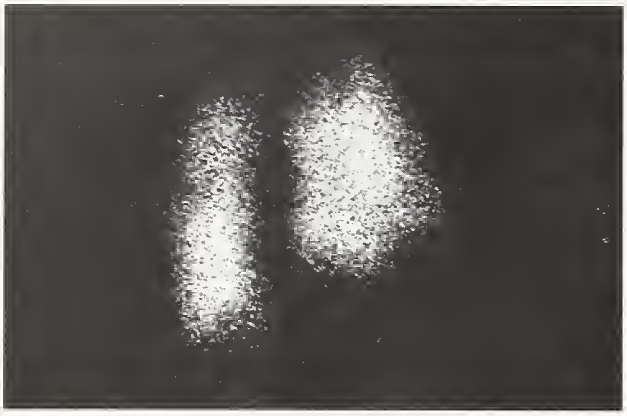

Figure 1
Technetium 99m pulmonary perfusion scan demonstrating a perfusion defect in the right lower lobe.

ing a non-obstructing thrombus in the proximal right subclavian vein. (Fig. 2) Systemic heparin was maintained for seven full days and conversion to oral Warfarin sodium was begun on the fifth heparin day. Symptoms resolved and the patient was able to be discharged from the hospital eleven days after the embolic event. Warfarin was maintained for three more weeks, but was subsequently discontinued on account of an episode of suspected perinephric bleeding. Further out-patient follow-up found the patient free of any upper extremity swelling or disability.

## Discussion

Vascular complications of fractures of the clavicle may result from immediate damage to the subclavian (or carotid) artery or to the subclavian vein. Laceration of either artery or vein may result in hemorrhage. *Arterial* thrombosis and occlusion may lead to distal ischemia, or damage to the arterial wall may result in aneurysm formation and the possibility of later distal emboli. *Venous* thrombosis may occur as an immediate complication or may be a delayed effect of costoclavicular compression. The potential for pulmonary embolism actually makes venous thrombosis a greater threat to life.

Venous engorgement of the upper extremity is an expected but not invariable result of subclavian vein thrombosis. Steinberg[1] documented two such instances, attributing thrombosis to malunion of the clavicle fracture with compromise of the space between the clavicle and the first rib.

In the patient described here, subclavian vein thrombosis did not follow malunion. Early open reduction had been carried out restoring the costoclavicular space. Whether the initial injury or the operative procedure initiated the thrombotic process is a matter of speculation, but it does seem logical to postulate intimal injury as attendant upon the initial direct trauma.

The clinical picture of pleuritic chest pain and dyspnea in this young patient was strongly suggestive of pulmonary embolus and infarction, and this suspicion was confirmed by radioisotope lung scan.

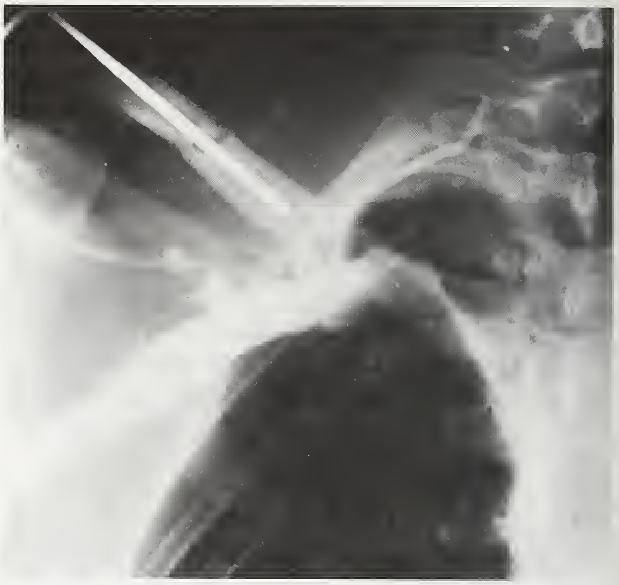

Figure 2
Subclavian venogram demonstrating large thrombus in the proximal right subclavian vein.

Although only pulmonary arteriography will provide a definitive diagnosis of pulmonary embolus, an abnormal perfusion scan in an otherwise healthy young patient (with a normal chest x-ray and venographic proof of major venous thrombosis) is confirmatory evidence mandating the use of systemic anticoagulation.

In 1949, Hughes[2] reviewed 320 cases of upper extremity thrombosis and expressed doubt as to whether non-fatal pulmonary embolus had ever occurred in this setting. There are several subsequently reported cases of pulmonary embolus secondary to subclavian vein thrombosis.[3] [4] [5] Steinberg[1] reported two patients with subclavian vein thrombosis following fracture of the clavicle, and in one of these patients pulmonary embolus was suggested by clinical findings and chest x-ray. However, more thorough documentation of pulmonary embolus subsequent to clavicular fracture has not been described.

The causes of upper extremity venous thrombosis are manifold[2]—trauma, effort, extrinsic compression (e.g. by substernal goiter or neoplasm), intimal injury (by intravenous catheters), inflammation of the upper extremity or systemic coagulopathy.

If subclavian vein thrombosis is suspected, measures to confirm or rule out this suspicion should be carried out. At the present time, contrast venography is the diagnostic method of choice, since non-invasive vascular diagnostic techniques have not been employed extensively enough in upper extremity venous disease to be sufficiently reliable. Campbell et al[4] found no corelation with symptomatology but did find non-invasive studies useful in evaluating the effectiveness of therapy. The decision for or against systemic anticoagulation should be based upon venographic findings. If the venogram does disclose thrombosis, the patient should be anticoagulated. And a ventilation-perfusion lung scan should be carried out even in the absence of pulmonary symptoms. The presence of a "silent" pulmonary embolus may influence further clinical management.

If anticoagulants are contraindicated, therapy must be individualized. Veal and Hussey[6] recommended ligation of the subclavian vein in such cases. Actual experience with thrombectomy is small. Although few *fatal* pulmonary emboli from upper extremity venous thrombosis have been reported, an embolus such as the one here reported could well prove fatal in a patient with underlying cardiac or pulmonary disease.

Since the injury itself was the most likely etiologic event in the present case, recommendations for or against open reduction of the clavicle should be governed by standard orthopedic criteria. Treatment should be directed to alleviating compression and minimizing the risk of pulmonary embolus.

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# Thyroid Taping: A New Method for Measuring Thyroid Nodules and Goiters

DAVID B. BALDWIN, M.D. AND DALE A. ROWETT, M.D.

**ABSTRACT—A new method to determine the size of thyroid nodules and goiters was evaluated in 25 patients. A questionnaire returned by 22 prominent endocrinologists revealed that there are no uniformly accepted means of measuring goiters or thyroid nodules. "Thyroid taping" was performed by placing a three inch strip of masking tape on the neck, and then tracing the thyroid gland. The tape was removed and placed in the patient's record. A thyroid tape provides a very efficient, neat, inexpensive, and accurate way of measuring goiters and thyroid nodules. Results are reproducible and subtle changes more easily determined than with current methods available today.**

The normal thyroid gland weighs 20 grams and has two lobes each measuring approximately 2 to 2½ centimeters in width and 4 centimeters in length connected by an isthmus 2 centimeters in width and 2 centimeters in length. Each lobe of a normal thyroid approximates the length of the terminal phalanx of the thumb ("rule of thumb").[1] How to accurately record abnormal findings of the thyroid antemortem is often difficult and unreliable.

These are various methods of measuring and recording thyroid nodules and goiters. An estimation of the weight of the gland (30, 40, 50 grams, etc.) or the size of the gland (1½, 2 or 3 times normal) or measurement of the gland or nodule in centimeters can be made. A picture of the outline of the thyroid gland and or nodules can be taken and placed on the chart and subsequent pictures taken to note any changes. The circumference of the neck can be

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measured or the height of the gland on either side of the isthmus can be determined by a ruler or calibers. Some physicians palpate the thyroid lobe while standing in back of the patient and then measure the distance between the index finger and third digit to determine the size. A method has been devised to outline the thyroid with a pen after palpation and then placing a moistened paper over the outline and recording the dimensions.[2] A thyroid scan can be used to correlate the findings with palpation.

We have not always found these methods to be reliable and helpful especially in follow-up assessments to determine whether a thyroid nodule or goiter has changed. Estimates by palpation with results expressed in size or weight can be in error by as much as 50 to 100%.[3]

We would like to introduce a new method to measure thyroid glands and nodules.

## Materials and Method

In the present study, the following letter was sent to 24 prominent endocrinologists and thyroidologists throughout the United States to inquire how they recorded the size of thyroid nodules and goiters:

> We are in the process of conducting an informal survey in preparation for publication of a paper concerning thyroid disorders. When a thyroid nodule or goiter is detected, we would be interested in knowing how you record your findings of the thyroid abnormality and how do you record subsequent changes in the thyroid condition?
>
> Which one of the following methods do you use (please check one):
>
> ___ 1. Sketch of thyroid on paper with recorded abnormalities.
> ___ 2. Photograph of patient with outline of thyroid.
> ___ 3. Estimation of thyroid size in gms.
> ___ 4. Estimation of thyroid size and nodular size in centimeters.
> ___ 5. Surface-outline method (gland outlined by ballpoint pen and moistened paper applied).
> ___ 6. Other. What technique? __________

Twenty-five of our own patients with either thyroid nodules or goiters underwent a careful inspection and palpation of their thyroid with the patient sitting on the end of an examining table and adequate lighting provided. Palpation was performed in front and in back of the patient displacing the trachea gently towards the side of the examination and having the patient swallow a glass of water.

When the examination was completed, the following steps were taken:

1. A single or double 3 inch strip of masking tape was spread across the anterior neck covering the thyroid.
2. The thyroid gland was then traced on the masking tape using a black pen and the "thyroid tape" completed by outlining any thyroid nodules with a red pen (see Figure #1).
3. The "thyroid tape" was removed from the neck and placed directly on the patient's clinical sheet to become part of his permanent record (see Figure #2).
4. Twenty of the patients had a repeat thyroid tape done again within one week without looking at the first tape to determine if the tapes could be duplicated without major discrepancies.
5. Fifteen patients had a thyroid tape done first by one of the authors and then by the other immediately thereafter without either seeing the other's tape.

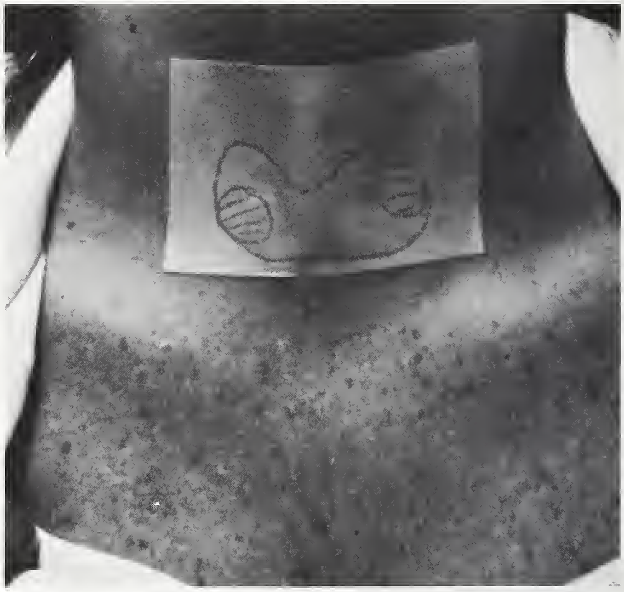

Figure 1

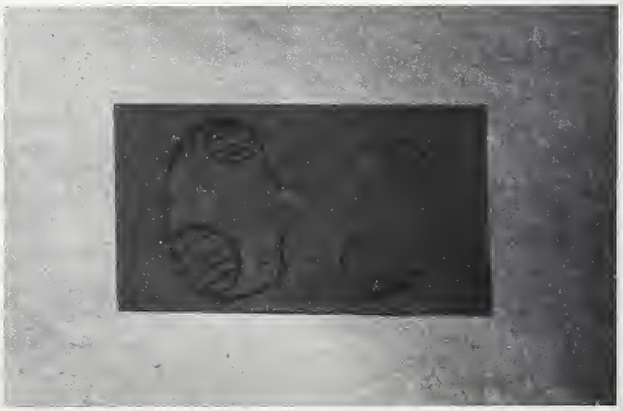

Figure 2

## Results

We had 22 of the 24 physicians respond to our letter inquiring how they measured thyroid nodules and goiters. Twenty physicians used at least two if not more methods. The most popular technique was estimation of the thyroid size in grams and nodules in centimeters (17 out of 22). A sketch of the thyroid was also a frequent method (12 out of 22). One suggested that he used calibers and one used a ruler. Thyroid scans were used as part of the measurements by two physicians. Only one used the surface outline method and only one took a picture of the patient and outlined the thyroid with a marker.

Of the 25 patients studied by us, 15 had a diffuse thyroid goiter; 4 had single nodules and 6 had a multiple nodular goiter. There were 24 females and 1 male. The average age was 42 with a range of 21 to 78.

Twenty of the patients had a second thyroid tape performed within one week of the first one. This was done to see how accurate the method would be. The repeat measures all came within ½ centimeter of the first.

Fifteen of the patients first had a thyroid tape made by one of the authors and immediately had another tape made by the other with neither knowing what the first tape demonstrated. Measurements in this group came within 1 centimeter of each other.

All of the 25 patients had a subsequent tape made within 3 months of the original to determine if this would be an accurate, feasible and practical procedure to use in clinical practice.

## Comment

We were very impressed by how many physicians responded to our questionnaire (22 out of 24). These physicians were prominent thyroidologists and endocrinologists and yet took time out of their busy schedule to respond. We were also impressed by the multitude of methods used in measuring thyroid abnormalities. There doesn't appear to be any one good method available especially in follow up assessments to detect any changes.

We found the "thyroid tape" very helpful in estimating the size of the thyroid nodules and goiters but even more helpful in estimating changes during subsequent visits. No attempt was made to compare the actual size of a gland or nodule at surgery or autopsy and the size as determined by the thyroid tape. However, we did attempt to see if the results could be reliably reproduced. That appeared to be the case even more accurately when done by the same individual.

The masking tape retains enough adhesiveness to stick firmly to the patient's neck and to the progress notes. The procedure could be completed in most cases in less than one minute. The patient does not find the procedure annoying and none reported discomfort. The technique is not messy and leaves no marks on the neck nor on the clinical record.

The "thyroid tape" is one method to record the size and shape of the thyroid gland and nodules. It provides a reliable means to detect subsequent changes. The "thyroid tape" is inexpensive, requires no radiation exposure, is not time consuming, is easy to do, and is reproducible. We suggest trying a "thyroid tape."

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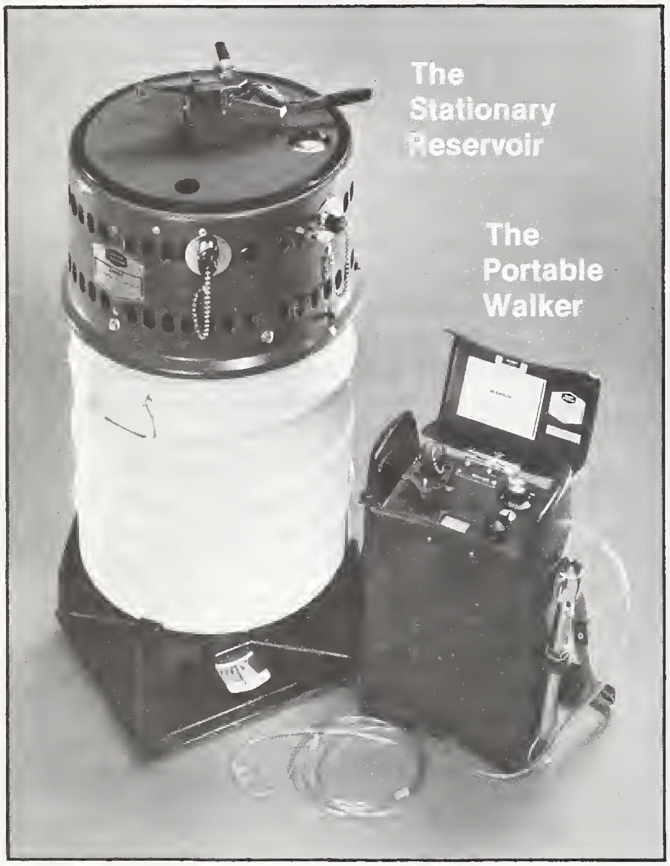

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# Medical Oncology: A Sub-Specialty That Has Come of Age

JOSEPH R. BERTINO, M.D. AND MARION E. MORRA, M.A.

Seven years have passed since the first national board exams were given in the sub-specialty of Medical Oncology. In Connecticut, as well as in many states across the country, medical oncology has become a major sub-specialty of internal medicine. Today, in Connecticut there are some 80 board qualified oncologists and hematologists. Approximately 20 of them are practicing the cancer specialty full time, either at the Yale-New Haven Medical Center or at the University of Connecticut Health Center. Nationally, the number of physicians board certified in oncology has grown to over 2,000 with a projection of 3,300 board certified oncologists alone by 1984. Factors important in emergence of medical oncology as a sub-specialty of medicine are the continued progress in the drug treatment of patients with cancer, and the need for internal medicine expertise for the medical care these patients require. With advances in adjuvant treatment of cancer with drugs, the medical oncologist is increasingly becoming involved in the initial evaluation of the cancer patient along with the surgeon and the radiotherapist.

## Hematology-Oncology Relationships

Because of the responsiveness of hematologic malignancies to chemotherapeutic agents, and the need for medical oncologists to be skilled in marrow aspiration/biopsy and interpretation and to understand problems dealing with bleeding, use of blood components in treatment, etc., the training of the medical oncologist usually involves hematology training as well. Dual board certification is possible, if trainees spend a minimum of 3 years in both sub-specialties while certificates in either board requires two years of training in that specialty. About half of the 80 Connecticut physicians practicing in the cancer specialty are also hematologists, many of whom have dual board qualifications.

## Training

There are approximately 500 training positions in medical oncology in this country, and since most programs are two years, the training programs generate 200 board qualified medical oncologists per year. It is estimated that by 1984-1985, there should be sufficient medical oncologists to meet the nation's needs. As a result of these considerations, there is a trend to decrease the number of training positions in this as well as other sub-specialties of medicine, and to shift emphasis in training programs to meet other needs, e.g., clinical pharmacologists and epidemiologists.

The training program at Yale accepts 5-6 trainees a year, and is academically oriented, since the fellows are supported primarily by a USPHS training grant. The program is run jointly by the sections of medical oncology and hematology, and most fellows spend 2 years in either hematology or medical oncology, but spend time in both sub-specialties. A few fellows have elected to stay on a 3rd year for further research training, or training leading to dual certification. In Connecticut, approximately 20% of the physicians specializing in the practice of cancer medicine were trained at the Yale University School of Medicine. Other trainees at Yale have gone on to become heads of medical oncology programs throughout the country.

## Oncology Units in Hospitals

There is a growing trend in the country of establishing oncology units in community hospitals, inasmuch as better care can be given to patients in a unit where specialty care is available, with nurses and other para-medical personnel, trained in cancer care in attendance. At least 11 hospitals in the state are offering this alternative to cancer patients. Although it is early to evaluate the effectiveness of these units,

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since most have been in existence less than two years and no formal evaluations have yet been reported, anecdotal experience does show that most patients are happy with the new units, and prefer returning to such a unit when the need for the hospitalization arises. At Yale, the oncology inpatient unit will expand from 12 to 22 beds this July, 15 of these beds assigned to research programs of the medical oncology section.

In addition to the inpatient units, there are two major cancer institutions in the state:

- The Yale Comprehensive Cancer Center is one of the 21 comprehensive cancer centers in the United States designed by the National Cancer Institute. Construction of new inpatient facilities will be completed by the end of the year, and completion of the Cancer Center is scheduled for March, 1980. Funding for this construction was derived from the National Cancer Institute, the State of Connecticut and Yale University.
- Uncas-on-Thames Hospital, a state owned facility, located in the northeast section of the state, specializes in cancer care, and houses the Phelps Radiation Therapy facility, staffed by Yale specialists.

## Many Cooperative Programs in the State

Probably more than most other states, there is a great amount of cooperative effort in the cancer field in Connecticut. It is probably due to several factors all of which allow the physicians to have frequent communications with each other:

(a) Many doctors trained at the Yale University School of Medicine and the University of Connecticut have stayed in Connecticut to open private practices across the state, allowing physicians who know each other to collaborate in cancer efforts;

(b) The Connecticut Oncology Association, a four-year old organization comprised of some 125 physicians, nurses and other health professionals, involved in the cancer field, meets regularly and fosters cooperative efforts;

(c) The American Cancer Society, Connecticut Divison, Inc., has active committees at 14 unit locations throughout the state and involves many of the cancer physicians on its working committees;

(d) The Connecticut State Medical Society has an active Cancer Coordinating Committee, involving cancer specialists from around the state;

(e) The Yale Comprehensive Cancer Center's Communications ·Office acts as a focal point for cooperative efforts, such as giving administrative support to the Connecticut Oncology Association and working with the other groups in sponsoring professional education efforts.

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This issue of *Connecticut Medicine* initiates a series of articles that will provide an update of the current status of treatment of malignant disease, with emphasis on drug treatment and supportive care.

# Current Concepts in Small Cell Carcinoma of the Lung

STEVEN GRANT, M.D. AND CAROL S. PORTLOCK, M.D.

### Introduction

During the last several years, a great deal of attention, both from basic scientists and clinical oncologists, has been directed toward small cell anaplastic carcinoma of the lung (SCC), commonly referred to as oat cell carcinoma. Recent experimental evidence has accrued supporting the notions that the cell of origin, the biological behavior, and the response to therapy of oat cell carcinoma differ in a very fundamental way from that of the other histological types of lung cancer. Indeed, despite the realization that small cell carcinoma is disseminated in the great majority of patients, the potential for prolongation of survival as a consequence of therapy in patients with metastatic disease is more dramatic in this entity that in any of the other subtypes of lung carcinoma. Two extensive reviews of this subject have recently appeared in the literature.[1] [2] The purpose of this discussion will be to highlight the distinguishing histopathological and biological characteristics of SCC, and to review recent therapeutic advances that have given clinicians a cautious sense of optimisn with regard to treatment of this tumor.

### Epidemiology

SCC accounts for 20-25% of all lung cancer, with an incidence of 25,000 new cases diagnosed annually. The association of this tumor with smoking is identical to that of the other histological subtypes. The male to female ratio in one large series was reported to be as high as 10:1, although this ratio is declining as the number of female smokers increases.

### Cell of Origin

There is substantial histochemical evidence that SCC arises from a neural crest derivative, the so-called APUD (Amine Precursor Uptake and Decarboxylation) cell of Pearse.[3] These cells contain intracytoplasmic granules that store catecholamines and their derivatives, and are thought to account for the wide variety of paraneoplastic syndromes associated with oat cell carcinoma. A proposed modification of the 1967 W.H.O. classification subdivides SCC into 3 histological subtypes: the classic oat cell (lymphocytoid), intermediate cell type (fuseform and polygonal) and a combined type. To date, there has been no clear-cut association between prognosis and histological subtype.

### Kinetic Considerations

SCC has both a high labeling index and short doubling time, relative to the non-oat cell varieties of lung cancer.[4] [5] In one study, the doubling time of SCC was found to be 30 days, compared to doubling times of 60 to 120 days found in epidermoid, adeno, and large cell carcinoma of the lung. The rapid growth rate of SCC has been invoked to explain both its predilection for dissemination, as well as its excellent response to chemotherapy and radiotherapy.

### Clinical Considerations—Presentation

Oat cell carcinoma generally presents as a centrally located tumor with frequent involvement of adjacent intra-thoracic structures. Cavitation is uncommon in the radiographs of patients with SCC, in contradistinction to epidermoid carcinoma, where it occurs fairly frequently. Unlike the other varieties of lung cancer, it is extremely rare for SCC to present in an asymptomatic individual.[7] Evidence for local spread, such as recurrent laryngeal nerve involvement or the appearance of a superior vena cava syndrome, occurs more frequently in this tumor than in the non oat-cell subtypes.[8]

### Ectopic Hormone Production

The hallmark of SCC is its frequent association with the elaboration of ectopic hormones, particularly ACTH and ADH, resulting in Cushing's Syndrome and the syndrome of inappropriate ADH secretion, respectively. Clinically detectable SIADH may occur

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in up to 8% of patients with SCC, and the incidence of Cushing's Syndrome may be as high as 4%.[9] Interestingly, recent work has shown that subclinical evidence of these syndromes, manifested by subtle abnormalities in water metabolism and elevations in immunoreactive ACTH, may be present in the majority of patients with SCC.[9 10] It should be noted that hypercalcemia secondary to ectopic secretion of parathormone is a rare occurrence in oat cell carcinoma.

### Clinical Considerations: Staging Patterns of Metastatic Spread

Perhaps the feature that most clearly distinguishes SCC from the non-oat cell histologies is its propensity for dissemination at the time of initial diagnosis. The early surgical series in oat cell carcinoma, which demonstrated 5 year survivals of 0-2%, suggested that this tumor did not behave like other lung cancers. In an analysis of 2000 patients, the American Joint Committee for Cancer Staging discovered that prognosis of patients with SCC was independent of whether the patient was initially judged to have State I, II or III disease. Corroborating evidence for this concept came from M.D. Anderson Hospital, where an extensive analysis of clinical variables demonstrated that the traditional factors associated with poor prognosis in lung cancer, such as the presence of pneumonitis, alectectasis, pleural effusion, mediastinal invasion, or metastatic lymph involvement, did not alter the survival pattern in SCC.[6] In addition, a number of series have shown that oat cell carcinoma has a particular predilection for bone marrow invasion, being present in as many as 50% of patients at presentation, in comparison to the 15-20% incidence in epidermoid and adenocarcinoma. Other studies have shown that intra-abdominal disease, manifested by hepatic, nodal, renal, and adrenal metastases could be documented in a small but significant percentage of patients at presentation.[12]

As a result of these studies, it became apparent that locally advanced or metastatic disease was present in the vast majority of patients with oat cell carcinoma at presentation. With this fact in mind, the V.A. Lung Cancer Study Group recommended that patients with inoperable SCC be classified into two groups: those with "limited" disease, (i.e. confined to one hemithorax, including ipsilateral positive scalene lymph nodes) and those with extensive disease (involving both hemithoraces and/or distant metastases). They found that the median untreated survival for patients in the first group was 3.1 months and for the second 1.4 months.[13] In fact, in the years following these recommendations, only two prognostic factors have been found to have any correlation with ultimate survival in SCC: the initial extent of disease ("limited" vs "extensive") and performance status. Thus, the prevailing opinion is that SCC is, in the majority of patients, a systemic disease, and should be treated accordingly.

### CNS Disease

With the improved responses to therapy in SCC, another clinical problem has become manifest: that of central nervous system disease. CNS involvement is found in SCC more frequently than in any of the other types of lung cancer; the post-mortem incidence in a large number of series ranges from 28 to 55%.[14] As many as 10% of patients with SCC will have CNS disease at the time of presentation; an additional 40% may be expected to acquire it during the course of their illness.[15] The types of metastases can be divided into three broad categories: cerebral, leptomeningeal, and spinal. 80% of all CNS metastases in patients with SCC are discovered prior to death; radionucleotide scans, computerized axial tomography, and lumbar puncture with CSF cytology are essential for antemortem diagnosis. Since the incidence of CNS disease has been shown to increase in parallel with prolonged survival, it is apparent that this clinical problem will assume greater importance as treatment regimens improve. The therapeutic implications of an increased potential for CNS involvement will be discussed subsequently.

### Therapy

The initial pessimism associated with small cell carcinoma rested on the observation that the untreated survival of patients with this tumor ranged from two to four months, depending on the initial extent of disease. Early therapeutic attempts were unable to alter survival patterns significantly. It was only with the advent of multi-drug chemotherapeutic regimens that the survival of these patients has increased substantially. Although the number of patients displaying "long term" (i.e. 2 year) survivals is still low, it is increasing. In fact, the median survival in several recent series involving patients with "limited" disease approaches 12 months, a result equal, if not superior to, series restricted to non-oat cell carcinoma. Since the likelihood of relapse decreases with increasing disease free survival, the potential for "cure" in a small number of patients with SCC appears to be an attainable goal. In this discussion, the separate results of surgical, radiotherapeutic, and chemotherapeutic regimens will be outlined, and recent data involving combined modality approaches will be summarized.

### Surgery

In 1973, Fox reported the results of a Medical Research Council trial comparing surgical to radiotherapeutic approaches in SCC.[16] The most striking finding of this series was the observation that there were no long-term survivals in the surgically treated group and that the median survival of this group as a whole in no way differed from previously reported untreated historical controls. Attempts to improve upon these surgical results with the use of pre and post-operative radiotherapy and single agent chemotherapy have all been unsuccessful; no significant survival benefit has accrued. With the growing realization that oat cell carcinoma is either locally advanced or widely disseminated at presentation, it became an established clinical dictum that this disease entity is essentially inoperable. More recently, the view that surgery is always contraindicated in SCC has been questioned by the results of a Veteran's Administration study in which 36% 5 year survivals following surgery were reported in asymptomatic patients presenting with a solitary pulmonary nodule and no evidence of further spread.[17] Nevertheless, for the average patient with SCC, surgery should not play a role in the therapeutic armamentarium. The possible role of cytoreductive surgery in conjunction with multi-agent chemotherapy will have to be resolved by future clinical trials.

### Radiotherapy

In view of the rapid doubling time and high labeling index of SCC, it is not surprising that it is a radioresponsive tumor. However, the initial enthusiasm for radiotherapy as single modality therapy for the disease entity has waned as a consequence of the very modest results achieved. Although response rates of 90% have been reported, significant survival benefit attributable to radiotherapy has been difficult to document. In the Medical Research Council Study previously mentioned, the mean survival of patients treated by radiotherapy alone was 6 months, significantly greater than that of the surgically treated group; yet the net survival advantage compared to similarly matched historical controls was slightly less than two months. The results of several other studies similarly revealed only very modest gains for patients treated with radiotherapy; in fact, in one study, patients with intrathoracic SCC treated with radiotherapy demonstrated a 17% 6 month survival compared to a 21% 6 month survival for untreated controls.[18] We have already alluded to the failure of pre or post-operative radiotherapy to enhance the survival statistics of surgically treated SCC. Because the survival rates in patients with oat cell carcinoma treated with radiotherapy alone are inferior to those of patients treated with multiagent chemotherapy, radiotherapy is currently judged to be inadequate as unimodal primary therapy in this disease.

The usefulness of radiotherapy in a palliative role is well documented, however. It has been reported to relieve bone pain secondary to metastases in 90% of patients so treated, and to improve symptoms secondary to cerebral metastases in the large majority of patients. When given in high dose fractions (i.e., 400 rads x 3 days), it has proven useful in the treatment of the superior vena cava syndrome as well as in spinal cord compression secondary to metastases. The role of radiotherapy as an adjunct to chemotherapy in CNS prophylaxis will be discussed in the following section.

### Chemotherapy

The most significant advances in the treatment of SCC can be attributed to the use of aggressive multiagent chemotherapy. The early enthusiasm for chemotherapy derived from a study carried out by the Veteran's Administration Lung Study Group which showed that Cyclophosphamide prolonged the median survival of patients with extensive disease to 17 weeks, compared to 6 weeks in untreated controls.[19] Subsequently, many drugs have been examined for activity in SCC, the most promising ones being Adriamycin, Methotrexate, Vincristine, VP-16-213, CCNU, Hexamethylmelamine, Mechlorethamine and Procarbazine, demonstrating responses in 15 to 45% of patients tested. Recently, multiagent chemotherapeutic regimens have shown impressive activity in this disease, with results translated into improved survival for patients with both limited and extensive disease. The Stanford Group, utilizing the "POCC" regimen, (Procarbazine, Vincristine [Oncovin], Cyclophosphamide, CCNU) achieved a median survival of 14 months in a group of patients, the majority of which had limited disease. Hansen and his group have been able to demonstrate a 38 week median survival utilizing a 4 drug regimen including Cyclophosphamide, CCNU, Methotrexate and Vincristine in patients with extensive disease.[25] Studies from the Southwest Oncology Group utilizing Adriamycin containing multi-drug regimens have shown similar excellent results. There is good reason to expect that with the incorporation of some of the newer agents into existing protocols that results may be improved even further.

### Combined Modality Therapy

In an early study, Bergsagel and his colleagues demonstrated that the addition of Cyclophosphamide to patients receiving radiotherapy for SCC extended the median survival from 31 to 44 weeks in patients with limited disease.[21] However, there has been a paucity of randomized prospective studies demonstrating the superiority of radiotherapy plus chemotherapy to chemotherapy alone in both limited and extensive disease. Data from the Southwest Oncology Group[22] as well as from the Stanford group already cited, failed to demonstrate any survival benefit from the addition of "involved field" radiotherapy to chemotherapeutic regimens in patients with extensive disease. The bulk of additional data appear to support these results. However, the adjuvant role of radiotherapy in combination with chemotherapy in patients with limited disease is more controversial, and conflicting results have appeared in the literature. Excellent results with combined chemotherapy and sequential "sandwich" radiotherapy have come from M.D. Anderson[23] where median survivals approaching 1 year and 15% 2 year survivals in patients with limited disease have been reported. Unfortunately data from the aforementioned controlled prospective studies is still lacking. Most recently, in a randomized trial comparing 4 drug chemotherapy to the same regimen plus radiotherapy in patients with limited disease, Hansen and colleagues found a superior median survival in the chemotherapy alone group (14 months vs. 11 months)[24] with a p value of < .01. The ultimate role for adjuvant radiotherapy in limited disease patients must await further clinical trials. Nevertheless, it is apparent that as the number of patients surviving 2 years or longer as a result of aggressive therapy increases, the potential for cure in a small number of these patients will rise correspondingly.

## Prophylactic Whole Brain Irradiation

In view of the increased survivals in patients with SCC and the correspondingly higher incidence of eventual CNS involvement, the concept of prophylactic whole brain irradiation has attracted a good deal of attention. To date, the utilization of drugs that cross the blood-brain barrier, such as the nitrosoureas, procarbazine, and VP-16, have not altered the incidence of CNS metastases significantly. In three controlled studies, the use of prophylactic cranial irradiation has resulted in a decrease in CNS metastases from 22% in the untreated group to 7% in the treated group, although the overall survival was not altered. Another problem that has arisen as a result of increasing survivals in patients with SCC is a disturbing increase in leptomeningeal and spinal metastases—potential sanctuary sites in patients treated only with cranial irradiation.

## Conclusion

It is apparent that the initial pessimism associated with the diagnosis of small carcinoma has given way to a sense of cautious optimism as a result of numerous therapeutic advances. Median survivals in this disease are beginning to match, and in some cases exceed, those associated with non-oat cell carcinoma of the lung. It is hoped that future clinical trials, involving the incorporation of newer agents into intensive chemotherapeutic regimens, the delineation of the role of adjunctive radiotherapy, and the utilization of prophylactic whole brain irradiation, will lead to results that surpass those already achieved.

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# Some Observations on the Evolution of Current Aortic Aneurysm Management

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**ABSTRACT—At the present time, the surgical technic for controlling abdominal aortic aneurysms has been unchanged for the past two decades and the surgical management of this disease appears for the time being to have reached a satisfactory plateau. The historical evolution of surgical approaches to aortic aneurysms is traced from the earliest descriptions of aneuryms 3500 years ago to the first successful resection of an abdominal aortic aneurysm by Charles Dubost of Paris in 1951. In the past 150 years the methods of aortic ligation, compression, wiring, wrapping, and resection have evolved and their use in the management of central aneurysms is shown to have been based historically on peripheral aneurysm treatment technics.**

While surgeons have learned to alleviate and palliate a variety of different afflictions which befall man, there are actually very few disease states which we can label as permanently solved or palliated by a surgical technic which goes unchanged over a decade or more. In the category of permanent cures by surgery are the diseases appendicitis and patent ductus arteriosus. Certain of the cardiac defects fall in this category also, but when we examine diseases which afflict other organ systems we find for example peptic ulcer disease, and in spite of a variety of different approaches on the part of the surgeon to manage the various complications of peptic ulcer disease, no single method is universally accepted and the surgical approaches tend to go full circle without ever coming to rest for a prolonged period of time.

No more formidable task faced the vascular surgeon than the approach to abdominal aortic aneurysms and it is a tribute to the ingenuity of both our predecessors and our current colleagues that a satisfactory resolution to this problem has in fact gone relatively unchanged for the past twenty years. It is obviously hazardous for us as momentary inhabitants of surgical history to declare any disease process under control or satisfactorily solved but at this moment in the history of vascular surgery, one would have to say that aneurysm disease of the abdominal aorta has for the time being a satisfactory surgical resolution.

The various approaches to the abdominal aorta were based on earlier experiences with extremity aneurysms and that saga must therefore be reviewed briefly. Before going back into the more distant past, it is important to establish that our current approaches have evolved over the last thirty years and that the crescendo of advances has been truly startling during this period of time. It seems most appropriate therefore to begin with a brief resume of how far we have come in the very recent past before we look to the distant past.

On March 29, 1951, Dr. Charles Dubost of Paris ushered in the era of modern abdominal aortic aneurysm management by resecting a large aortic aneurysm in a 50 year old man and replacing it with a 15 cm. length of thoracic aorta taken from a 20 year old girl three weeks previously.[1] Debakey, Cooley,[2] and many others reported progressively larger series of aneurysm management by aortic homograft replacement but it soon became apparent that despite a variety of different ways of preserving these homografts, many of them failed after a period of time due to dilatation, deterioration, and disruption. While we shall see later that there were earlier attempts to substitute prosthetics in the arterial tree, it was Arthur Voorhees in 1952[3] who first noted that a textile tube, which he called Vinyon "N", bathed in a

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rapidly-moving blood stream developed an endothelial-like surface.

Based on this and other work, it was determined in the late 1950's that a prosthetic fabric graft was by fai a more ideal aortic substitute and after trials of fabrics such as Army Air Corp parachutes, sailcloth, and other materials, the woven and knitted Dacron grafts were developed and are now widely used. While the refinement of our present method for managing abdominal aortic aneurysms has occurred during the past twenty years, the technic for approaching these aneurysms is a modification of principles explored for many centuries.

In writing about the history of aneurysms, D. deMoulin observed that the Greek term *aneurysma* is undoubtedly from the verb meaning to enlarge or dilate. It is not known for certain whether the ancient Egyptians were aware of aneurysms in that one must be very cautious in applying modern terminology to ancient case reports. But deMoulin found in the Ebers Papyrus written about 1550 B.C. the following account which certainly sounds like the description of an aneurysm:

> When thou considereth a swelling of the vessels on any part of the man's body and thou findst it globular and firm under thine fingers when going, it is separated from the flesh, it is not large, it does not show the surface.
>
> Then thou shalt say: this is a vessel's swelling, a disorder I will treat. It is the vessels that cause it. It originates from an injury upon the vessel. Then thou shalt apply to it a treatment with the knife; this knife heated in fire the bleeding will not be considerable.[4]

Although arteriosclerosis has often been noted in the pathological examination of Egyptian mummies, no aneurysms have been found. No reference to aneurysm is made in Greek medicine up to the 2nd century A.D. when Galen[5] wrote the following:

> When an artery is opened the disease that occurs is called an aneurysm. It happens in consequence of the skin in the neighborhood of a wounded artery cicatrizing whilst an ulcer remains in the vessel, which neither becomes agglutinated nor cicatrized nor filled up with flesh. Diseases of this description are known by their pulsating and by their disappearing entirely when pressed upon; the contents of the tumor which we have elsewhere shown to be thin and bright blood mixed with much subtle spirit is warmer than that contained in the other vessels. If an aneurysm be wounded the blood is spouted out with so much violence that it can scarcely be arrested.

Aneurysms were not mentioned in the Hippocratic collection nor were they noted in de re Medica written by Celsus. In some of the earliest documents from India different types of aneurysms were described with a variety of treatments suggested including compression with the thumb or a wooden or metallic rod. Also suggested was opening of the aneurysm with removal of the capsule or sac and hemorrhage to be controlled by thermal cauterization. It was advised that tumors of the vessels were rather difficult to cure and that the surgeon should not operate if the tumor was fixed or immovable nor if it was situated near vital organs.

The earliest post Alexandrian comment on aneurysms came from Rufus of Ephesus.[5] It was only a brief remark that injury to an artery might be followed by aneurysm if the wound cavity around the vessel was not filled up in time by new tissue. This rather casual warning suggested that aneurysms were at least recognized by the Alexandrian surgeons.

Antyllus[6] was probably the first who clearly distinguished between true and false aneurysms but his works have all been lost except for scattered fragments. He did, however, write an essay on aneurysms and described the difference between traumatic and nontraumatic types. Antyllus in the 2nd or 3rd century A.D. operated on the peripheral aneurysms by ligating them above and below and then scooping out the contents of the aneurysmal sac without hemorrhage. It was his feeling that the sac should be left in place rather than excising it. He avoided religiously those aneurysms which occurred in the axilla, groin, or neck usually because of their dimensions and also because of the difficulty in approaching them. It should be noted that these arterial ligations were being carried out 1400 years before the circulation itself was described by Harvey in 1628.

According to Porter,[7] Philagrius of Macedon in the 4th century first practiced extirpation of an aneurysm. Aetius,[5] physician to Emperor Justinian in the 6th century, recommended ligation and division of the artery proximal to the aneurysm then opening of the sac, and intrasaccular ligation of the artery at the distal end of the sac. Centuries later, Rudolph Matas[8] advocated a similar approach and this will be mentioned subsequently. Aetius made the following comment however concerning aneurysm management:

> As regards the treatment, it is well known that those aneurysms which occur in the neck or head are considered by surgeons to be past all remedy. For as soon as the aneurysm is laid open so large a quantity of blood and of vital spirit escapes that the patient frequently dies in the hands of the surgeon.[5]

Paulus in the 7th century advised extirpation of the peripheral aneurysms having previously applied a ligature above and below but cautioned the following:

> We must not attempt to cure large aneurysms affecting the armpits, the groins, the neck or other places on account of the great size of the vessels in these situations.

Following these advances up to and including the 7th century, the art of detecting and managing peripheral aneurysms remained basically unchanged for many hundreds of years.

Vesalius[9] in 1555 described aneurysms of the thoracic and abdominal aorta for the first time, but it was Ambroise Pare[10] who wrote the more extensively.

In 1582 Pare made the first observation of an association between atherosclerotic disease and the presence of an aneurysm. He wrote:

> The reason why some aneurysms become large with a bony circumference is that the arterial blood becoming heated and boiling causes the coats of the vessels first to dilate and enlarge and then to give way; and taking from the neighboring parts matters similar to themselves in order to reunite, thus occasion a large or small tumor according to the capacity of the part. Then little by little the circumference of the tumor dries and hardens like a vessel becoming cartilaginous and then osseous by a material in efficient cause, as stones are formed in the kidneys and bladder, for the earthy matter of the blood being dried and thickened by the unusual heat adheres to the coats of the artery and of the parts that it occupies thus becoming hard and bony.[5]

We hear also from Pare the recognition of thrombus within a peripheral aneurysm and the lethal result from ischemia. He continues,

> besides in very large aneurysms there is frequently no pulsation; and pressing upon them the blood cannot be forced back into the artery both because it is in too large quantity and because it concretes into a thrombus and afterwards putrifies, as it is no longer kept up by the natural heat of the heart from which great pain ensues, then gangrene and mortification of the part, and lastly death.[5]

It was Pare in the mid-1500's who ligated the vessel above and below the aneurysm but with the expectation that coagulation of the contents would occur, he did not open the sac.

While Pare appears to have been the first to note that atherosclerosis was an accompanying feature of aneurysmal disease, there is some controversy concerning who was first to recognize syphilis or other infections as etiologic factors. Giovanni Lancisi in his book de Aneurysmatibus[11] which appeared posthumously in 1745 attributed to lues a case of popliteal aneurysm he had seen. This is said by deMoulin to be the first time that syphilis was implicated as the cause of an aneurysm but others feel that Pare was the first to make this observation.

Antonio Scarpa[12] wrote a monograph on aneurysms in 1804 and based this on a comparative analysis of normal and pathological tissues, showing for the first time that an aneurysm was not just a simple dilatation of an artery but was the result of profound alterations in the layers of the vessel wall.

Trauma as a cause of peripheral aneurysm, which we now would recognize almost certainly as a false aneurysm, was a well known cause of pulsatile mass and frequently disaster. Laceration of an antecubital vein for bloodletting, used in the management of a variety of disorders, was not uncommonly accompanied by inadvertent injury to the brachial artery and aneurysm formation in this region was a frequent malady in the 15th and 16th centuries. Pare's pupil, Jacques Guillemeau in 1594[5] described his management of a young man in whose arm such an aneurysm had formed after bloodletting. Proximal ligation of this aneurysm was carried out, following which the sac was opened and the intrasaccular thrombi were removed. The aneurysm itself was then filled with lint in the hope that it would heal by the usual process of suppuration and scarring. This particular patient was fortunate enough to have adequate collateral circulation so that his arm was preserved and on this basis Guillemeau recommended his technic as an entirely appropriate treatment for antecubital aneurysm.

In addition to ligating aneurysms or wrapping them with tourniquets, opening them and stuffing them with materials such as lint or copper sulfate was not an uncommon approach. Perhaps the ultimate in this technic was practiced by Dionis, better known for his leather protective boots in the treatment of varicose veins, whose custom it was to chew up a large wad of paper and stuff it into the aneurysm. It can be understood perhaps, with this as an example of his arterial work, why he is better known for his management of varicose veins.

While the circulation itself and the collateral supply was described by many, in particular John Hunter, it is not widely recognized that much of the existence of this collateral network was established on the basis of major arterial ligation in the management of peripheral arterial aneurysms. Anel[13] in 1714 gained considerable renown by curing a traumatic brachial aneurysm with a ligature very close to the sac, but it was John Hunter in 1785 on the basis of observations which he had made, who suggested a more proximal ligature to spare the collateral circulation. Hunter had established by his experiments that the anastomosing vessels of the limb in their natural state would be capable of immediately taking on increased flow sufficient to supply circulation to the area below the point at which the main artery was tied. In addition, it was Hunter who first understood the importance of local arterial disease in the causation and treatment of aneurysms of the lower extremity and these recognitions of etiology, anatomy, and physiology led him to apply a ligature considerably proximal to the popliteal aneurysm itself. The clinical experience of Mr. Hunter was reported in detail by a letter from his brother-in-law, Mr. Everard Home, and published in the London Medical Journal in 1786.[14] Mr. Home reported in great detail of this approach and recounted the rationale of Mr. Hunter:

> "From these considerations, suggested by the accident of the artery giving way, which happened several times to Mr. Hunter, he proposed, in performing this operation that the artery should be taken up at some distance from the diseased part so as to diminish the risk of hemorrhage and admit of the artery being more readily secured should any such accident happen. The force of the circulation being thus taken off from the aneurysmal sac the cause of the disease would, in Mr. Hunter's opinion, be removed; and he thought it highly probable that if the parts were left to themselves the sac with the coagulated blood contained in it might be absorbed and the whole of the tumor removed by the actions of animal economy which would consequently render any opening into the sac unnecessary."

We have recounted to this point several of the earliest observations and case reports concerning peripheral arterial aneurysm and have dwelled heavily on the ligature method of control. It was generally accepted that the more centrally located aneurysms were simply beyond the possibility of treatment.

But during the 19th century when attempts to deal with iliac and aortic aneurysms were made, compression and irritation, in addition to ligation were some of the methods used, again based on the earlier experiences with the peripheral aneurysms. As we recount the tales of the more intrepid surgeons of the 19th century we shall refer again briefly to the earlier work on which their attacks on the central aneurysms were based.

It should also be noted at this point that the operations we are describing took place before the days of asepsis and anesthesia, and that restraint of the patient was made possible only by a combination of alcoholic spirits, heavy twine or rope, and the muscle power of selected burly compatriots. Realization of this makes even more incredible what we are about to recount from the first part of the 19th century.

Until the principle of aortic aneurysm resection became widely accepted in the mid-Twentieth century, there were five basic approaches used by surgeons in attempting to control the progressive and inexorable expansion of the central aneurysms. These were ligation of the abdominal aorta proximal to the aneurysm, compression of the aorta, wiring of the aneurysmal sac, endoaneurysmorrhaphy, and production of progressive fibrosis by tissue irritants. Each of these methods has its important place historically in the progress toward aortic aneurysm resection with Dacron graft replacement.

It was reported by William H. Porter in 1839, that Mr. W. Stevens, a surgeon on the island of Santa Cruz, had ligated an internal iliac artery for aneurysm in the year 1812[7] but the first ligation of the human aorta in 1817 is attributed to Sir Astley Cooper.[15] His classical narrative of 1825 recounting his experience is excerpted here briefly:

> Charles Hutson, a porter, age 38, was admitted into Guy's Hospital on the 9th of April, 1817, for an aneurysm in the left groin situated partly above and partly below Poupart's ligament. The swelling was very much diffused and pressure upon it gave considerable pain. On the third day after he had been in the hospital, the swelling increased to double its former size and extended from 3 - 4 inches above Poupart's ligament to an equal distance below it and was of great magnitude. . . . He was occasionally bled, kept perfectly quiet, and pressure was applied on the tumor . . . about half-past two o'clock, in consequence of a sudden mental agitation, bled profusely and became exhausted; but Mr. Key, then my apprentice, succeeded in preventing immediate dissolution by pressure. At 9:00 the same evening I saw him and found him in so reduced a state that he could not survive another hemorrhage with which he was every moment threatened . . . and as the only chance which remained of preventing his immediate dissolution by hemorrhage was by tying the aorta, I determined on doing it. The operation was performed as follows: . . .
>
> I then made an incision three inches long into the linea alba giving it a slight curve to avoid the umbilicus: one inch and one-half was above, the remainder below the navel. Having divided the linea alba I made a small aperture into the peritoneum and introduced my finger into the abdomen; and then with a probe pointed bistoury enlarged the opening into the peritoneum to nearly the same extent as that of the external wound. During the progress of the operation only one small convolution of intestine projected beyond the wound.
>
> Having made a sufficient opening to admit my finger into the abdomen I passed it between the intestines to the spine and felt the aorta greatly enlarged and beating with excessive force. By means of my fingernail I scratched through the peritoneum on the left side of the aorta and then gradually passed my finger between the aorta and spine and again penetrated the peritoneum on the right side of the aorta.
>
> I had now my finger under the artery and by its side

> I conveyed the blunt aneurysmal needle armed with a single ligature behind it; and Mr. Key drew the ligature from the eye of the needle to the external wound and the needle was withdrawn.
>
> The next circumstance which required considerable care was the exclusion of the intestine from the ligature, the ends of which were brought together at the wound and the finger was carried down between them so as to remove every portion of the intestine from between the threads: the ligature was then tied and its ends were left hanging out of the wound. The patient's pulse both immediately and for an hour after the operation was 144 in a minute. I applied my hand to his right thigh immediately after the operation and he said that I touched his foot so the sensibility of the leg was very imperfect. . . . He remained very comfortable until the following evening when he vomited.
>
> 27th - 7 o'clock a.m. had passed a restless night and had vomited at intervals; pulse 104 weak and small; pain in his head; great anxiety of countenance; very restless and his urine dribbled from him. He gradually sunk and died at eighteen minutes after one o'clock having survived the operation 40 hours.

From Cooper's first ligature of the abdominal aorta in 1817 to 1920, none of the eighteen patients in whom the aorta was occluded for abdominal aneurysm survived, deaths occurring from erosive hemorrhage, peripheral and spinal cord ischemia, infection, and shock. A variety of different ligature materials was used including various types of tape, aluminum bands, and silver wire. Cotton tapes, fascia lata and other materials did not enjoy their popularity until after 1920 and the cutting through of various ligatures in these abdominal aneurysms as well as in the control of the more peripheral aneurysms which we discussed previously was not uncommon. In spite of the few successes subsequently reported by Bigger,[16] Elkin,[17] and others, the approach of ligating the aorta for aneurysm did not gain widespread acceptance and other avenues were being developed.

The treatment of peripheral aneurysm by compression was employed well over 200 years ago primarily in cases of traumatic aneurysm. Carlo Guattani,[5] in the year 1772 in Italy, was the first to employ compression in a case of popliteal aneurysm by applying pressure directly upon the sac and also by bandaging the entire limb, believing that the aneurysm could be controlled by squeezing the blood out of the sac into the peripheral arteries as water would be squeezed out of a sponge. The edges of the artery were then thought to be brought into apposition and to become adherent although it was felt that blood would continue to flow through this channel.

A number of mechanical compression devices were designed but it was Jonathan Knight of New Haven in 1848 who first suggested the digital pressure of aneurysms, and such pressure was maintained by relays of medical students for two days or more in the hope that the aneurysmal dilatation could thus be controlled.[6] Unfortunately, gangrene of the extremity was a common accompanying feature of these technics and at least half the patients in whom compression was employed for a peripheral aneurysm succumbed to complications. Nevertheless, it was on this basis of compression of peripheral aneurysms that William Murray, lecturer on physiology in the University of Durham and consulting physician to The Children's Hospital, Newcastle-on-Tyne, managed to control an aortic aneurysm by pressure in 1864.[18] Using what was described as a horseshoe tourniquet made to open wider than usual and allowing the trunk of the body to be grasped, Dr. Murray applied this device on two occasions to his patient using light chloroform anesthesia. After the second application of the device it was noted that not only was the pulsatile character of the mass abolished but that the femorals had lost their pulsations and that the lower extremities had become cold. Upon recovering from the anesthesia the patient noted numbness of the extremities and other symptoms of severe ischemia but by the following day some sensation had returned to his feet and remarkably enough within a few days the patient was up and about having had his aortic aneurysm thrombosed by this feat of external compression.

Again, the method of introducing wire into an aortic aneurysm, had its origin in the management of peripheral aneurysms. The purpose of this technic was to improve the structural support of the aneurysm by the wire itself and by deposition of clot on the wire. Before aneurysms were wired, Meade[10] reports that J.B. Monteggia in 1813 sought to obliterate the lumen of a peripheral aneurysm by injecting a sclerosing fluid into it. In 1833 C.H. Pravaz[10] pierced the sac of an aneurysm with needles through which he passed an electric current. A similar attempt in 1838 was made by Benjamin Phillips[10] but it was not until 1845 that J.P.E. Petrequin[10] of France succeeded in occluding an aneurysm by this method. This led to C.H. Moore's[19] introduction of cold fine wire into a thoracic aneurysm in 1864, but how he managed to pass 26 yards of wire into the aneurysm is not known.

Silver wire introduced percutaneously through an insulated needle and heated by a battery induced current was described by Corradi in 1879. The resulting ionization product deposited at the surface of the wire was depended upon to encourage the initiation of blood clotting. G.H. Colt who reviewed his many years of experience with introducing multiple wisps of wire into the sac has recounted in fascinating detail his observations with this method.[21] Most surgeons found that wiring of aneurysms was an unsatisfactory approach and the deposition of fibrin and clot on coils of wire introduced into the aneurysm frequently was not accomplished. Arthur H. Blakemore writing much later in the mid 1940's and recounting his experiences with this technic,[22] noted that in order for the method of wiring aneurysms to be efficient, the induction of mass clotting had to fulfill a number of criteria but of most importance it had to afford an adequate and efficient clot-stimulating surface to the passing blood.

The basic method of wiring aneurysms was carried out by passing designated lengths of a wire loop through an insulated needle into the aneurysm lumen, and most surgeons heated the protruding two ends of the wire to encourage clotting. The ends were then pushed into the aneurysm with a blunt stylet and the procedure repeated with another length of wire which the surgeon dispensed from a reel, usually suspended at the surgeon's eye level over the abdominal wound. Controlling the destination of these wire loops was a difficult prospect and it was not uncommon for one or more loops to come to rest in the cardiovascular tree considerably removed from the intended position. In addition to wire a variety of different materials, including horsehair, was deposited into these aneurysms.

Rudolph Matas' technic of endoaneurysmorrhaphy, first used in 1888, was employed by him in the treatment of peripheral arterial aneurysms.[8] For the first time the aneurysmal sac was opened and the orifices of the various vessels sutured closed from within, this approach being similar to the intrasaccular ligation advocated by Aetius in the 6th century which we have previously noted. The sac was then obliterated by repeated rows of sutures thus occluding the main arterial channel but unfortunately producing distal gangrene in a number of patients. However, Matas was the first to describe the suture closure of the communicating orifice in a saccular aneurysm with preservation of the circulation. In managing aortic aneurysms, however, Matas himself preferred either ligation, or the Moore-Corradi method of wiring.

In 1910 Alexis Carrel[23] reporting on a series of experiments he had done on the thoracic aorta said that it was rational to think that some aortic aneurysms could be removed. After partial resection of the wall of the aorta in an animal he had been able to put on a patch of artery or vein and even a piece of peritoneum. In addition, he had succeeded in substituting for a part of the abdominal aorta a tube of rubber sheeting. Circulation through this tubing had continued for several months and he further stated that entire segments of veins and arteries could be transplanted into arteries.

In the 1930's and 40's, a variety of different technics was developed in an attempt to produce irritation and support around the aneurysmal wall of the abdominal aorta in order to contain a progressive expansion. Cellophane was highly popular as a periaortic irritant. Numerous other substances such as asbestos powder, talcum powder, quartz, and aluminum phosphate were used to stimulate fibrous tissue formation. Cutis grafts enjoyed a brief period of popularity but were found to be reabsorbed and to be poor producers of fibrosis. In 1951, Grindlay and Waugh placed a thin sheet of polyvinyl sponge over the wall of four abdominal aneurysms with the expectation that fibrous tissue would grow into the sponge and strengthen the sac.[24] Others used a variety of different materials to enclose the aneurysm sac including Orlon, Nylon, and eventually Dacron.

While the technic of wrapping aneurysms, either alone or in combination with wiring, enjoyed a brief popularity, it had as a disadvantage a very major dissection of an exceedingly hazardous anatomic structure and was abandoned fairly rapidly when a more definitive procedure was developed.

At the June 1951 meeting of the Society for Vascular Surgery, N.E. Freeman[25] presented an ingenious method of placing a homologous vein segment into the widely opened aneurysmal sac, stitching the vein to the proximal and distal segments of the aorta, in the hope that the clotted blood formed between the vein inlay graft and the aneurysmal sac would produce an added support with the lumen of the vein serving as the central channel. His immediate result in the one case which he presented was gratifying and it is interesting to note that basically this is the modern technic except that the Dacron tube graft rather than a homologous vein graft is used but is inlaid into the aneurysm sac much in the way that Freeman described in 1951, but without allowing or depending upon clotted blood to act as a graft reinforcer.

It was not long thereafter that Dubost reported from Paris the successful homograft replacement of an abdominal aortic aneurysm and the rest is today.

In conclusion, we can examine in historical perspective the development of our modern methods of aortic aneurysm management and recognize that ligation and control lie at the foundation of our surgery for this disease and that vascular reconstruction now allows a more normal restoration of physiology and dynamics. Such is generally true of most successful solutions in surgery. But how crucial it is for progress that statements such as the following from *Lancet* of 1828[26] do not discourage the more intrepid among us:

> "On Sunday, the 12th Ultimo, Mr. James, one of the surgeons of this Institution, placed a *ligature* upon the aorta in a case of *aneurysm* of the external iliac artery. In one of the Exeter papers, it is stated that the operation was *"successfully performed"*; but it was that kind of success of

which the Irishman boasted when he had killed his hog, for the patient survived the infliction of the knife only two or three hours. It is an appalling operation, and we hope not to hear of its repetition . . ."

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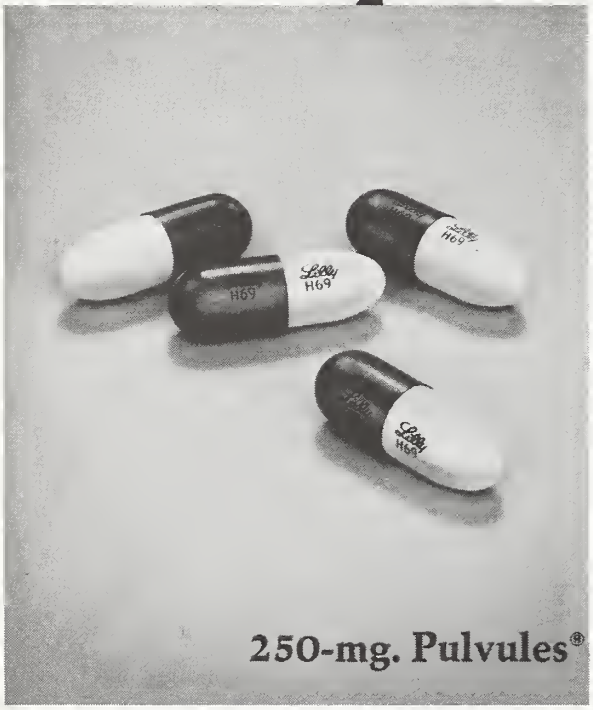
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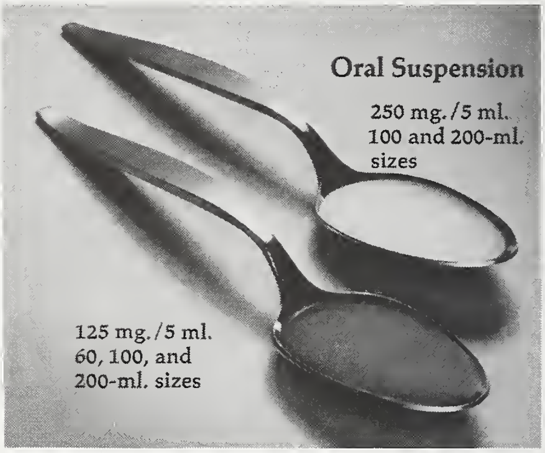
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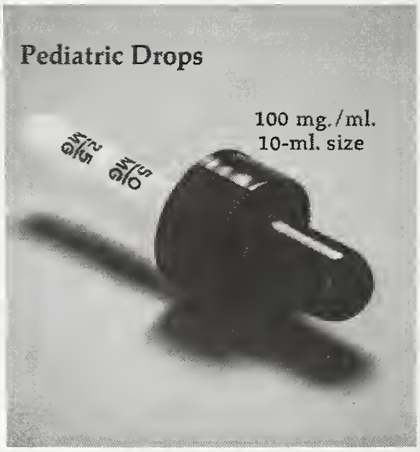
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# Indications for Tonsillectomy and Adenoidectomy: Phase I

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## Introduction

The National Institutes of Health consensus development program brings together biomedical research scientists, practicing physicians, consumers, and others as appropriate, in an effort to reach general agreement on the safety and efficacy of a medical technology. That technology may be a drug, device, or medical or surgical procedure.

Following consensus meetings, summaries of conclusions and recommendations issued by consensus panels are widely distributed to the research, practicing, and lay communities. All shades of opinion are reflected in those summaries.

At NIH, the Office for Medical Applications of Research (OMAR) is responsible for coordination of the consensus development program. OMAR assists the individual NIH institutes, which sponsor the conferences, in this effort.

At this meeting held on July 20, 1978 the Ad Hoc Advisory Panel on Tonsillectomy and Adenoidectomy reviewed the report, "Planning a Multicenter Study of Adenotonsillectomy," the result of a grant, NS—13166—01A1, funded in 1977. This grant, funded by NINCDS as a result of an application from the School of Public Health, Department of Epidemiology, University of Pittsburgh, was an outgrowth of recommendations of a Consensus Development Workshop held in June 1974 on Tonsillectomy and Adenoidectomy partially funded by NINCDS at the request of an Ad Hoc Committee of the American Council of Otolaryngology.

Dr. David G. Hanson, Acting Director, Communicative Disorders Program, NINCDS, briefly reviewed the history of the NINCDS involvement in tonsillectomy and adenoidectomy consensus. Dr. Seymour Perry, Associate Director for Medical Applications of Research, NIH, briefly related the interest of NIH, the USPHS and DHEW in the topic and reinforced the need to provide solid scientific data on which to base decisions on the indications for the surgical procedures of tonsillectomy and adenoidectomy.

The Panel members had been provided in advance with copies of the Report to be reviewed as well as with appropriate background material including the Proceedings of the Tonsillectomy and Adenoidectomy Workshop.

Consideration of the Report was focused around detailed discussions of each of the Report's recommendations.

It was the consensus of the Panel that study of tonsillectomy and adenoidectomy was necessary and desirable. However, a large number of problems in and disagreements with the Report's recommendations were identified. A number of alternatives to the Report's recommendations were suggested and discussed. Several of the Panel members expressed concern that subject selection criteria for proposed studies should more closely approximate currently accepted criteria employed in medical practice although it was realized that selection criteria will necessarily be somewhat arbitrary. The well recognized difficulties in recruiting sufficient numbers of subjects to be randomized into a study was discussed. There was consensus that a careful period of observation prior to randomization was most desira-

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Copies of booklet "NIH Consensus Development Conferences Summaries from 1977-78," may be obtained from the Office for Medical Applications of Research, Building 1, Room 216, National Institutes of Health, Bethesda, Maryland 20205. Copies of 1979 individual conferences are also available.

ble. The problems of a control group were discussed including the difficulties of anticipated attrition from the control groups due to continued disease or because the subjects became much better. The relative merits of a design utilizing each patient as his or her own control were discussed.

It was the consensus of the Panel members that tonsillectomy and adenotonsillectomy for sore throat need not be evaluated in the same study as an examination of adenoidectomy, adenotonsillectomy, and/or tympanostomy tubes for otitis media with effusion. The differentiation of pharyngitis from tonsillitis was pointed out as being an important factor. There is little question that tonsillectomy is effective treatment for tonsillitis while that procedure may have little effect on recurrent pharyngitis. However, most of the Panel members agreed that it is usually very difficult to differentiate pure pharyngitis from pure tonsillitis and that this differentiation is not usually made in patients presenting complaints or in the usual identified indications for surgery. It was noted that for many reasons a study of tonsillectomy and/or adenoidectomy and/or tympanostomy tubes for middle-ear disease may be much more clear cut in outcome and certainly is important.

The Panel did not accept the recommendation of the Planning Report that a large multicenter national study is the only feasible means of obtaining sufficient data. The Panel commended the valuable work accomplished in the Planning Study and concurred that the Planning Study Report represents a very useful document in the planning of future studies.

Unanimous consensus was reached by the Advisory Panel on the following recommendations:

1. A prospective clinical trial to determine the efficacy of tonsillectomy and adenotonsillectomy in reducing morbidity due to sore throat and nasal obstruction is necessary and desirable.
2. A prospective clinical trial to determine the efficacy of adenoidectomy and adenotonsillectomy in reducing morbidity due to otitis media with effusion is necessary and desirable.
3. The efficacy of tympanostomy tube insertion in concurrence with adenoidectomy and adenotonsillectomy in reducing morbidity due to otitis media with effusion should be studied in the second prospective clinical trial.
4. Single and multiple center trials are feasible methods of gathering sufficient data regarding the efficacy of tonsil, adenoid and tympanic surgery in the reasonably near future. Feasibility studies must be considered in the context of specific proposed protocols.
5. The most effective method of support should be utilized after review by Institute staff and may include either grant or contract mechanisms.

**The Report's Summary Recommendations are:**

1. A prospective clinical trial to determine the efficacy of tonsillectomy and adenotonsillectomy in reducing morbidity due to recurrent tonsillopharyngitis and the efficacy of adenoidectomy and adenotonsillectomy in reducing morbidity due to otitis media with effusion is necessary and desirable. Currently available scientific knowledge is not adequate to serve as a basis for individual treatment decisions or for quality assurance policies.
2. The efficacy of tympanostomy tube insertion in concurrence with adenoidectomy and adenotonsillectomy in relieving morbidity due to otitis media with effusion should be studied in the same prospective clinical trial.
3. A multicenter clinical trial is the only feasible method of gathering sufficient data regarding the efficacy of tonsil, adenoid and tympanic surgery in the reasonably near future.
4. An ethical and scientifically valid protocol to study the efficacy of such surgery has been proposed, reviewed by an expert committee and by a large group of potential clinical investigators, and is included in this report.
5. The proposed multicenter study can be completed in five to five and one-half years, in six to ten clinical study centers, at a cost of $7.5 to $8.1 million.
6. The most effective organization of such a study will be achieved through a single grant or contract to a coordinating center, which will, in turn, enter into performance based contracts with collaborating clinical centers.
7. Knowledge gained from such a study appears likely to modify significantly current practices regarding tonsil, adenoid and tympanic surgery, reducing the number of such procedures performed on children unlikely to benefit from surgery and better defining which children are likely to benefit from surgery. If such new knowledge reduces the incidence of such surgery by even a small proportion, the reduction in national medical care costs will far exceed the cost of the study.

# Professional Licensure

MICHAEL PERTSCHUK, J.D.

**Our culture is dominated by professionals who call us "clients" and tell us of our "needs." Morticians advise us of what is required for a "decent" burial. Sex therapists counsel us about what is required for intimacy. Professional hypertrichologists diagnose and treat our "excessive and unsightly" facial hair. Our children's education requirements are determined by professional teams of speech therapists, learning disability specialists, child psychologists, social workers, school administrators, and guidance counselors.**

Our very language has transformed the word "need" from a personal verb, dependent for its content on the one who feels it, to an objective noun. "Needs" are now somehow separate and apart from people; they have become the objects of professional competence, beyond our private competence to diagnose. We speak of the "delivery" of health care, legal services, or social services; and of the "achievement" of mental health or degrees of educational competence, as if we were talking about commodities manufactured in uniform portions for those who lack them.

The increasing ubiquity of the professionals has had an insidious, intimidating effect. We lack confidence in our unprofessional abilities to diagnose our private needs from personal experience. Increasingly, we go to professionals to reveal our needs, not just to service them. The professional stockbroker, real estate agent, insurance agent, doctor, dentist, lawyer, pharmacist, auto mechanic, architect, interior decorator, psychiatrist, mortician, family planner, organizational development specialist—all now counsel us about our needs, advise us about what we should want, and then service these prescriptions.

This combination of diagnosis and service is often efficient (how wasteful it would be to require that the diagnosing physician or auto mechanic first put the body back together again before offering to repair it). But the combination is open to subtle abuse. How can the diagnostician be relied on to understand our unique preferences, our own particular willingness to trade off quality against price, our unique aversion to risk?

And since it is difficult or impossible for us to evaluate whether the recommended services match our personal preferences, how can the diagnostician be relied on not to act in ways calculated to maximize his profits, by recommending services on which he stands to make the greatest gain?

Too often the most conscientious diagnosticians, who rely most heavily on time-consuming personal interviews, who make the effort to guide, explain, and listen carefully to our complaints or queries, earn far less than those who opt for more costly, highly technological diagnostic tools. We are directed to diagnostic centers, filled with complex equipment, which analyze our physical, psychological, emotional, or financial needs. And those diagnosticians who prescribe a change in personal habits or routines are likely to earn far less than those who proceed to apply the techniques and remedies for which they've been trained and on which they profit. Too often the result is misdiagnosis, and over-prescription.

It's estimated that 33 cents of every dollar spent last year on auto repair went for unnecessary work. Last year two million Americans underwent operations they didn't need, at a cost of 10,000 lives and four billion dollars. And personal expenditures for lawyers, physicians, dentists and other professionals are increasing at a rate faster than the average for all goods and services in the economy.

Ironically, licensing is both a response to, and a

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MICHAEL PERTSCHUK, J.D., Chairman, Federal Trade Commission. A recent address before the American Enterprise Institute Occupational Licensure Conference, Washington, D.C.

cause of, this problem. It is a response because, at least theoretically, it brings to bear the government's comparative advantage in policing against misleading diagnoses and excessive service. If consumers are unable to evaluate bundles of diagnosis and service, then arguably the government should step in and set minimum standards, to ensure the competence and integrity of those who offer such bundles. Variations on this argument are sounded to justify most licensing schemes. Indeed, some concerned consumer groups now urge that auto mechanics be licensed in states where they are not, and that the licensing of lawyers and physicians be even stricter in order to guard against the kind of shoddy service that fuels inflation in these industries and is at least partly responsible for a dramatic increase in malpractice suits.

But licensing is a cause of the problem to the extent that it becomes a vehicle for the dominance and exclusive authority of a profession, legitimizing its monopoly on discerning and remedying needs, and enforcing its mystique by limiting access to special knowledge. Too often it is the members of a particular occupation who seek licensing as a means of enhancing their prestige and incomes. At a recent session of one state legislature, occupational groups advanced bills to license themselves as auctioneers, well diggers, home improvement contractors, pet groomers, electrologists, sex therapists, data processors, appraisers, and TV repairers. Hawaii licenses tattoo-artists. New Hampshire licenses lightning-rod salespeople.

The evolution of certain occupations from being collections of individual sellers to tradesmen to certified professionals and ultimately to licensed professionals is well known. Barbers have been transformed into cosmetologists; garbage collectors into sanitary engineers; undertakers into grief counselors; clerks into policy analysts. Specialized courses of study are required, displacing apprenticeship and on-the-job training. Qualifying exams, citizenship and residency requirements, and professional fees are imposed on new entrants. Professional journals appear, Washington offices are opened to lobby for favorable legislation, and public relations firms are retained to ensure a favorable image. The profession develops status political strength, and exclusivity. And each of these attributes re-enforces the others.

It is hardly surprising that, once licensed, the profession is in a position to determine how much competition it will tolerate. Licensing boards, dominated by members of the profession, may act like any other cartel—adjusting entry standards to protect the incomes of established practitioners. It is not unusual for boards to reject higher percentages of applicants during periods of economic downturn when their services are in less demand. Nor is it unusual for them to restrict advertising, promotion, and innovative ways of delivering their services, thereby making it more difficult for new entrants to compete.

Thus, like medieval guilds, the licensed professions can maintain their privileged positions regardless of market forces. Study after study has shown that licensing results in higher direct costs to consumers. Indirect costs, in the form of foregone innovation and experimentation, are higher still.

But what about quality? Higher prices may be justified if quality is improved, if there are fewer cases of misdiagnosis and excessive service.

The fact is that all too often licensing bears little relation to quality. Several years ago the FTC compared the price and quality of TV repairs in Louisiana, where repairers were licensed, to the District of Columbia, where no licensing was required. Result—prices 20 percent higher in Louisiana, but virtually the same incidence of unnecessary repair in both places. Other studies have shown that uncontested divorces handled by parties themselves without lawyers resulted in the same incidence of legal error as when handled by lawyers, and that clinical laboratories licensed by states have the same incidence of inaccurate clinical test reports as unlicensed laboratories.

Indeed, licensing boards rarely monitor quality. Most professionals, once licensed, are licensed for life. You need periodic re-examination in most states to drive a car or pilot an airplane, but not to continue practicing as doctor or lawyer. Between 1967 and 1973, only 400 doctors were disciplined by state boards for professional incompetence—an average of one-point-six (1.6) per state, per year.

When licensing renders certain services unavailable to segments of the population who can't afford to pay for licensed professionals consumers may end up with poor and dangerous quality of the do-it-yourself variety. One study shows that states with the most restrictive systems for licensing electricians also have the highest rates of deaths from accidental electrocution.

Are we bound, then, to a closed circle of professionals identifying and adjudicating needs, professionals admitted to practice by professionals, and self-policing by professionals? I don't think so.

A rebellion is brewing against the privileged position of professionals. Blame it on a revival of Populism, on a resurgence of frontier self-sufficiency, on two decades of economic analysis focusing critically on occupational licensing, or on an increased skepticism about government regulation. Whatever, the barriers to entry and innovation erected by professionals are beginning to fall.

The Supreme Court has struck down state laws prohibiting price advertising by pharmacists and lawyers for routine goods and services. Last year the Federal Trade Commission lifted restrictions on price advertising by optometrists, opticians and ophthalmologists. We've issued a consent order barring the American Society of Anesthesiologists from deterring its members from working under contract with hospitals. FTC staff have recommended a rule requiring funeral directors to disclose a full range physician control over Blue Shield boards, as well as impediments to competition imposed by the licensing of lawyers, accountants, and dentists.

Private groups and the states have also taken steps to open up the professional marketplace. The American Veterinarian Medical Association and the American Psychological Association, after discussions with us, have revised their codes of ethics to permit members to advertise. A committee of the American Bar Association has proposed streamlining its disciplinary procedures. California has placed a majority of public members on most of its licensing boards. Twenty-three states have enacted some form of sunset law, enabling the states to closely scrutinize their licensing boards. In Minnesota, no group can submit proposed licensing legislation without satisfying the state's Legislative Audit Commission that licensing is necessary.

More and more we are discovering that professionals are not markedly different from any other sellers who offer their services in trade. Nothing dissolves a mystique faster than seeing lawyers advertise inexpensive legal services like used car dealers advertise special deals. Making visible the commercial underpinnings of the professions is therapeutic. It fosters a healthy skepticism. It teaches us that, as in all other commerce, a vigorous competition, coupled with adequate consumer information, assures the optimum range of quality at the lowest possible price.

Certainly we need be concerned about fraud and deception, just as we're concerned about it with door-to-door sellers. But there are means of guarding against fraud and deception that are far less restrictive than licensing. Certification offers one alternative. It provides consumers with information about the competence of the seller without creating a barrier to entry. Separation of diagnosis from service—the "second opinion" which allows consumers to comparison shop—offers another. (That's why we required, in the FTC eyeglass rule, that eye examiners provide consumers with a copy of their prescription.)

At the Federal Trade Commission we are committed to working with you to comprehend and remedy vestigial and unjustifiable restrictions on the marketplace for professional services. You should know that generally we view FTC rulemaking as a less attractive alternative to effective cooperative efforts with state and local officials and concerned citizen groups. We are sensitive to concerns about the extension of federal authority into areas which historically have been the province of the states.

A primary role for us is to employ our legal and economic resources to design and fund essential studies to compare the effects of alternative regulatory systems on price and quality. We can help serve as a clearinghouse for information and counsel on initiatives to reform regulation of the professions. And we can help identify critical issues for competition and consumer protection in professional regulation.

At the same time, we have an obligation to carry out our Congressional mandate to police unfair methods of competition and unfair and deceptive practices in the marketplace. We will continue to act, where in our judgment professional regulation violates the basic tenets of our laws of competition and consumer protection and where there exists no serious alternative reform effort.

Perhaps when enough barriers have been removed, and professionals must rely to a greater extent on their reputations for competence in providing service—when the discipline of the market forces them to innovate, cut costs, and simplify their processes—perhaps then we'll be less intimidated by them. Perhaps then we'll all be more skeptical about their abilities to tell us what we need, and more sure of our own abilities to discover what we want. Perhaps then, when we consumers feel empowered to deal with professionals on an equal footing, we'll lay greater claim to our own felt needs.

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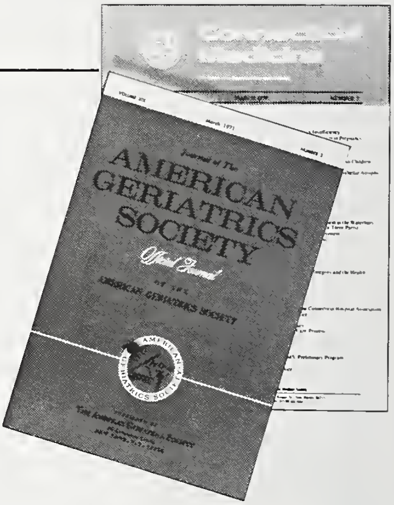

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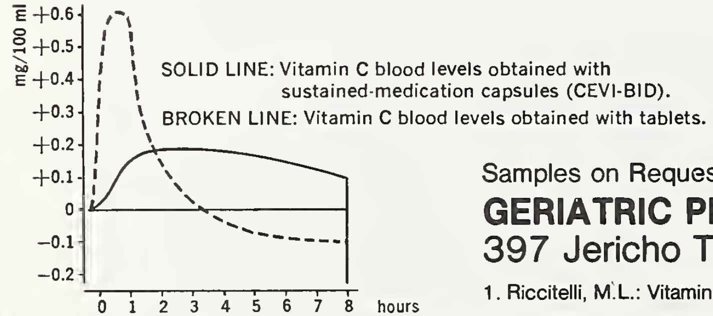

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# Sabbatical from Solo Private Practice

JOHN P. CALLAN, M.D.

When I told my colleagues that I planned to give up private psychiatric practice for a year's fellowship in medical journalism, my colleagues and my family were skeptical and thought it a passing whim. After they learned I was serious, their reactions ranged from gross incredulity to envy. One physician, alarmed by what he considered such foolishness on my part, suggested that I, not my patients, required counseling as I was obviously struggling with a mid-life "passage." Another admired my courage but doubted my wisdom. A sabbatical year, one of the perquisites of academic medicine, is something not considered part of solo private practice and therefore is thought to be unavailable to private practitioners. But that need not be so, even though the few private physicians who think about a sabbatical are seldom able to transform their thoughts into action.

Several reasons are decisive. Classically, private physicians establish practice routines that persist throughout their professional lives, shortly after hanging out their shingles. Such routines seldom include long periods away from practice, doing other things that might be thought self-indulgent by our founding fathers. Patient responsibility, salary considerations, coverage, guilt, the necessity to alter routines and uncertainty about the future all conspire to keep a private physician going around in the same groove like a phonograph needle, resisting change. But I was lucky; I was able to leave the rut and "do my thing" for a year, after ten years of solo private practice. Like Walter Mitty, though I was one thing, a psychiatrist, I longed for opportunities in another field. In my case, it was medical communications. I was fortunate in that my fantasy coincided with an opportunity that came along when I was able to grasp it with both hands. I was awarded the Morris Fishbein fellowship in medical journalism by the American Medical Association. This meant that I would spend my year working as a senior editor on the Journal of the Association, and I would be based in Chicago. The decision to accept the fellowship was both easy and difficult; it was easy in that the fellowship was in a field which intensely interested me and difficult in that I had to give up a practice that I had struggled to develop and that my family did not wish to relocate to Chicago. Following discussions, it was agreed that I would commute back and forth to the midwest from Connecticut, on weekends.

The headquarters of the American Medical Association is a square box-like building which looks surprisingly symmetrical for a structure that has undergone several expansions over the years. Originally located on Dearborn Street in Chicago it now occupies a whole block, stretching to State Street, just north of the famous Loop. About 1,000 employees, most of whom are not physicians, occupy its nine floors. Each floor houses different departments, such as membership, meeting-planning, advertising, legal and legislative affairs. I became part of the JAMA team, assigned to the Scientific Publications Division on the eighth floor, next to senior editors John Archer and Sam Vaisrub on one side and Bill Barclay and Terry Southgate, editor and deputy editor on the other.

The first thing visitors to the AMA notice is the tight security. Everyone entering the building must be checked by guards, and packages are screened. This is a holdover from a decade ago when student activists attacked the AMA, and a disgruntled "Sore throat" publicized confidential memoranda. First-time visitors seldom fail to comment on the security, but old-timers take it in their stride.

The initial eight weeks of my fellowship were spent at the elbows of JAMA's senior editors. I sat in on thrice-weekly manuscript meetings and watched how manuscripts were processed, categorized, reviewed, rejected or accepted. By observing and discussing editorial decisions, I learned to make judgments and critically assess the relative merits of papers. Originality in articles was sought by JAMA, and the editors asked; Was the work truly original and not a follow-up of a previously published study, such as covering a longer period or a larger group of patients? Was the methodology sound or suspect, and the data valid? What about the results and conclusions: were they consistent with the findings or did the authors speculate and extrapolate beyond their data? Was the review of literature comprehensive and up-to-date or did the researchers select references that exclusively supported their contention, thereby indicating bias? And finally, like a fast-food restaurant, what about

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the take-home message: was the research relevant, who would care about it, and will it contribute to medical knowledge? Would a physician who reads it be able to practice better medicine as a result?

Papers that passed initial scrutiny were then sent to expert reviewers, specialists in the area covered, and their views were sought. In the final verdict, their opinions counted heavily as to whether or not the paper would appear in print. Not many papers passed muster and only 15%, of the close to 4,000 manuscripts submitted annually, were published. The time lapse from submission of an article to rejection was about a month, from submission to acceptance about three months, and submission to publication not less than six months.

After learning the JAMA ropes, I was assigned to *American Medical News,* the weekly tabloid newspaper that reports the state of American medicine as of the prior week. Here the atmosphere was different. Where JAMA was sedate and scholarly, *American Medical News* was shirt-sleeves and sweat, and deadlines were more critical. *American Medical News* differed from other medical periodicals received by physicians by having up-to-the-minute coverage of medicine's socio-political scene. The other publications operate more slowly and present more dated material, which still may be "news" because the reader has not heard of it previously.

My first *American Medical News* assignment was to the Washington, D.C., office of the AMA, where approximately 40 employees keep their fingers on the nation's health legislative pulse and attempt to ensure that it remains healthy. After attending a briefing, I went to the Capitol and watched Senator Kennedy's National Health Insurance hearings. My account of the staged production appeared later in *American Medical News.* Shortly afterward the Jonestown, Guyana tragedy occurred. Within a week, as fast as the major news magazines, *American Medical News* carried medically oriented accounts of the mass suicides and exclusive interviews, including one by me with the former Yale psychiatrist Hardat Sukhdeo, M.D., a native of Guyana. Later I traveled to Montclair, New Jersey to interview the son of a prominent surgeon who had written a book on his experiences with the "Moonies."

Subsequently I wrote book reviews for *American Medical News* . One of these was a favorable critique of Ann Landers' encyclopedia. After reading it, she telephoned to thank me and then asked me to send six copies of the review to her New York publisher!

Following my work at *American Medical News* , a stint with the medical news section of JAMA was scheduled for me. In its front-of-the-book department, JAMA staff reporters present new developments in medicine before such information is published as a formal paper. Other medical journals say this is improper because they think a formal paper with complete data is the only way critical assessment of the material can be made by physicians. Well-known editors have displayed strong emotions when discussing this issue. Medical meetings became my beat for the medical news section. I covered the North American continent, filing features from Las Vegas to Boston, and Montreal to St. Kitts Lesser Antilles. My Caribbean assignment to report on Dr. Frank Ervin and Yale Professor of Psychiatry Dr. Gene Redmond's primate laboratory was a welcome relief from the mountains of snow covering Chicago. The story appeared in JAMA in May.

Throughout the winter and into the spring I hopped around the country and commuted to Connecticut. But travel was not always easy. First the weather disrupted air traffic, then there was the United Airlines strike, followed by the grounding of the DC-10's. My flights were frequently changed or cancelled and bookings were hard to get. I was at O'Hare Airport waiting to take off when the American Airlines jet crashed that fateful memorial Friday. I had watched the passengers board the plane just a few minutes earlier, and I flew over their funeral pyre shortly afterward. Since then, even though I hold a commercial pilot's license, my anxiety mounts on take-off. My alarm is not relieved by the knowledge that two of the other airlines I used during the year have since had fatal crashes on routes I flew.

Other features of the fellowship were learning printing, design, layout, advertising and circulation, in fact everything necessary to edit and manage a medical journal. I had the opportunity to compare other publications with JAMA by spending time at the offices of the *New England Journal of Medicine, Chicago Medicine, Medical Economics, Archives of Internal Medicine, Annals of Internal Medicine,* the *Florida State Medical Journal* and others.

Now that my year is over I have returned to Connecticut, to part-time medical practice, part-time writing and part-time editing. It has not been difficult to return to clinical medicine, and after reading so many scientific papers and journals during the year, I probably know more medicine than ever. When colleagues ask what I learned that was valuable I respond, "Seeing the big picture."

Even though my technical writing and editing skills have improved, technique is nothing without an overview. Before I accepted the fellowship I occupied a narrow position in central Connecticut which limited my horizons. My world was the geographic area in which I lived, and my interests centered around it—the hospital where I worked and my practice. Now my perspective has broadened, and I can see not only how the total sum is greater than its parts, but why. I would encourage other private practitioners to take a sabbatical, if they feel the urge.

# Professional Standards Review Organizations: Data Collection and Management

*The following is a report of the AMA Council on Medical Service to the House of Delegates at its Interim Meeting in December, 1978.*

The Council on Medical Service and its Ad Hoc Committee on PSRO present this report on PSRO data collection and management as we believe serious, imminent threats to the integrity of PSRO data systems exist. This report addresses two issues, both concerning PSRO involvement in multiple-user data systems:

I. The Department of Health, Education, and Welfare's decision to collect the Uniform Hospital Discharge Data Set (UHDDS) through fiscal intermediaries and agents, rather than through PSROs.

II. Guidelines for PSRO participation in data consortia.

## I. The Uniform Hospital Discharge Data Set

On May 24, 1978, the Under Secretary of the Department of Health, Education, and Welfare, Hale Champion, indicated a "tentative preference" for collecting the Uniform Hospital Discharge Data Set (UHDDS) through fiscal intermediaries and agents rather than through PSROs.* Currently PSROs collect what is called the PSRO Hospital Discharge Data Set (PHDDS), which consists of the UHDDS with some additional PSRO-related elements.

A memorandum issued in late August, 1978 from the DHEW Assistant Secretary for Planning and Evaluation to the Under Secretary outlined a strategy for implementation of the tentative decision for fiscal intermediaries to serve as primary collectors of the UHDDS. DHEW is apparently moving ahead with Mr. Champion's decision despite considerable opposition from PSROs and despite the identification of several problems which may result from DHEW's plan.

The tentative decision to change the data collecting and processing system is based on Section 19 of P.L. 95-142 enacted in October 1977, which called for the establishment of a "uniform system" of collecting discharge data on all federal patients—although Section 19 does not specify who the collector and processor should be. According to DHEW officials, selection of fiscal intermediaries as collector/processor has three purposes: (1) to reduce the cost of collecting the UHDDS information, (2) to eliminate the current "overlap" in collection systems, and (3) to obtain "better" diagnostic information on patients in anticipation of more sophisticated reimbursement mechanisms.

Specifically, PSROs are primarily concerned with: (1) the ability of fiscal intermediaries to collect the necessary data and to provide high quality data to the PSROs in a timely fashion; and (2) to fiscal intermediaries' ability to maintain the confidentiality of the data.

Following its review of this matter, the Council on Medical Service and the Ad Hoc Committee on PSRO agree with the concerns cited above, and also see broader implications if this policy is allowed to stand. The Council is convinced that collection of basic medical data by fiscal intermediaries will have the ultimate result of merging medical information with fiscal data. The Council is of the opinion that the confidentiality and integrity of patient and physician data will rapidly deteriorate if DHEW implements this policy.

Under the proposed system the PSROs would essentially be phased-out of the role of collecting its own data over a two to three year period. These existing PSRO data collection systems, although not ideal, have been developed after considerable analysis, discussion, and review by all the relevant parties. This changeover would eliminate the systems which PSROs have developed over a five-year period. Also, the proposed system would be costly and would delay the output of quality data. PSROs would be dependent upon fiscal intermediaries to assure the supply of high quality discharge data.

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*The UHDDS is part of the required standard data set collected by the PSROs. This data set includes, for example: patient identification, admission and discharge dates, attending and operating physician identification, diagnoses, etc. Presently, PSROs report this data to DHEW on a quarterly basis, omitting the patient and practitioner identifiers.

Other concerns are: (1) Submission of UHDDS could well be made an additional condition of hospital participation and reporting requirements, thereby requiring hospitals to cooperate by contract if they wish to stay in the program; (2) DHEW might interpret the intent of Section 19 of P.L. 95-142 to include collection of UHDDS for *all* patients; (3) DHEW has raised again the need for a common identifier for physicians and patients; and (4) fiscal intermediaries will be required to join the Cooperative Health Statistics System (which in some states are controlled by state agencies) where they exist. Also questioned is the possibility that fiscal intermediaries will be placed in a position of unfair advantage by having access to billing and medical data for patients insured by other third-party carriers.

This Council views DHEW's decision as a serious encroachment on the right of PSROs to control their own data environment, which may lead to a reduction in the ability of PSROs to impact on the quality of care rendered by physicians in their respective areas. Further, the Council is convinced that current operational PSRO data systems could accommodate the legislative intent of Section 19 of P.L. 95-142. Therefore, the Council on Medical Service *recommends that:*

> The AMA should continue to oppose the transferring of responsibility for collection and control of confidential information in hospital discharge data from the PSRO to the fiscal intermediary. Furthermore, the AMA should continue to negotiate with DHEW to assure that PSROs have a continuing role in the maintenance of control over confidential data containing individual patient and physician identifiers and that such identifiers not be required in any uniform system of reporting hospital discharge data.

### II. Guidelines for PSRO Participation in Data Consortia

The Council is aware that PSROs across the country are evaluating the necessity and desirability of participating in cooperative data agreements such as data consortia. The Department of Health, Education, and Welfare is encouraging PSROs and other health-related agencies to aggregate their data collection, processing and analysis.

Data consortia, joined into voluntarily, and not under state or Federal government control, can be cost-efficient as well as provide a mechanism for valuable health data interchange. As costs are shared among producers and users, the actual costs to the participating agencies may be lower. In addition, the consortium can "purchase" a level of expertise and experience that they could not afford within their own staff structure.

Existing data consortia vary widely in organizational structure, function, and membership. Some of these arrangements are sorely lacking in proper data safeguards, and in some cases effectively limit a member's control over its own data.

Based upon these concerns the Council on Medical Service *recommends the following guidelines for PSRO participation in data consortia.*

(1) Data consortia under certain circumstances are recognized as a useful and appropriate vehicle for health data interchange. Organized medicine should support PSROs' voluntary participation in a private, locally organized data consortium.

(2) Upon entering into the data consortium, each participating group should identify the specific data items it seeks to obtain. The data so identified should be selected and released on the basis of "need to know," which has been demonstrated to the satisfaction of the members of the consortium. The data should not be released on the basis of "perceived need" alone.

(3) Each party to the data consortium should specify which of its data items it classifies as confidential. The data designated as confidential by one member of the consortium should not be accessible to any other member of the consortium or to any other individuals or agencies.

Each member of the consortium should have absolute veto power over access to those data items that have been designated as "confidential."

(4) Centralized data systems have the potential for reducing the member-agencies' abilities to obtain information on a reasonable "turnaround" basis. Therefore, working agreements should specify a maximum "turnaround" time, preferably within a written contract.

(5) Any entity with multiple users and multiple support will be pressured to be responsive to all its members. All the participating agencies should make certain that minimum needs are specified by contract and that emergency situations will be accommodated.

(6) Any participating group should be free to withdraw at any time from the consortium if it determines that its data needs are not being adequately served, or that the confidentiality of its data has not been maintained. The withdrawing group should have the right, by previously established agreement, to have all of its data either physically returned, or destroyed.

# St. Raphael's Wins CAT Scanner in Court

**Hospital of St. Raphael**
**v.**
**Commission on Hospitals and Health Care**
**of the State of Connecticut**

**Decision of the Superior Court**
**Judicial District of New Haven**

**September 5, 1979**

### Memorandum

This matter arose by virtue of the defendant Commission's denial of the appellant hospital's application for approval of its proposed purchase of a Computerized Axial Tomography Unit (hereinafter referred to as a scanner) at a cost of $615,000.

Many points are not in dispute. A scanner is a highly sophisticated computerized X-ray machine. Its development has been of great benefit in diagnosing blood clots, tumors and other masses within the body and accurately locating them. Its use can elimate the need for exploratory operations. In short, all parties to this action agree that its use should be available to a community the size of greater New Haven. The issue presented here is whether a scanner should be located at the appellant hospital in view of the existence of other scanners within the City of New Haven.

The Commission did not seriously question the qualifications of the plaintiff hospital as to staff, physical plant, etc. Commission did question the plaintiff's estimate of savings to be realized by use of the scanner and pointed out that 35 intracranial operations were performed there in fiscal 1976, fifteen short of the fifty set forth in the guidelines of the Commission.

The actual reasons set forth for the refusal were as follows:

A. The need for additional C. T. scanning services has not been substantiated. The region presently has excess capacity and the hospital has offered inadequate indicators of unmet need.

B. The proposed service would duplicate services provided by the health care facilities which in the aggregate are operating at less than full capacity. Thus, the addition of another C. T. scanner to the New Haven area would have the effect of duplicating services and result in excess costs to the community.

In doing so, the Commission cited Connecticut General Statutes § 19-73k which authorizes it to consider duplication of scanner services in the area served and the community or regional need. Section 19-73m requires that the defendant balance the expense of a proposal in excess of $100,000 with the area need for the program among other things. The other matters that the Commission was required to consider were not mentioned as the basis for its denial.

The evidence revealed that the applicant had recently completed an extensive expansion program known as the Verdi Unit. Part of that program included construction of new emergency room facilities, together with appropriate accommodations for a scanner. Approximately $500,000 had been and remains earmarked for the purchase of a scanner. I find that the plaintiff was aggrieved by the final decision of the Commission and is therefore entitled to judicial review as authorized by Connecticut General Statutes § 4-183.

The evidence indicated that three scanners are located in New Haven. Two are at Yale-New Haven Hospital, and one belongs to the Temple Medical Group, a private organization of physicians. Since the Temple Medical Group is private, the Commission cannot regulate its purchase of equipment.

> "The evidence in this case clearly demonstrates that the immediate availability and access to a C.T. scanner is necessary to the proper practice of neurology and neurosurgery in modern

> society. It further shows that neurologists or neurosurgeons are best able to supervise and interpret C.T. Scans involving neurological problems. Furthermore, the evidence shows that a C.T. Scanner is extremely beneficial to patients with neurological problems. Its use often eliminates potentially dangerous and painful invasive diagnostic techniques, and, indeed, it also often eliminates the need to hospitalize patients. The use of a C.T. Scanner has been shown by the evidence presented at the trial frequently to lead to great reduction of the total cost of medical care and treatment for neurological patients. Therefore, there is no rational relationship between the regulation of the defendant physicians and the purpose of the statute. To regulate these defendants by requiring the approval of their purchase of a C.T. Scanner would violate their right to practice their profession free of unreasonable governmental interference."
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> *Connecticut Commission on Hospitals and Health Care* v. *Neuro-Diagnostics P.C.*, No. 143812, at 10-11, (Comm. Pleas, Hartford Cty., Dec. 20, 1977).

It follows that the Commission cannot regulate its use and therefore cannot require that it be available for any particular time periods.

Dr. Richard Greenspan, head of the Radiology Department of Yale-New Haven Hospital, testified that one of the scanners at that institution was outdated and not used. The other is on loan to the hospital for use in research. It has been used for clinical purposes because it is the only workable scanner available. Clearly, the owner could require its return at any time although it has graciously refrained from doing so up to the present.

The above evidence indicates that there is no workable scanner *owned* by an institution under the control of the Commission that is available for use by the New Haven community.

This court is fully conscious of the prohibitions of Connecticut General Statutes § 4-183g against substituting its judgment for that of the agency as to weight of evidence on questions of fact. Here, however, the reasons given by the Commission establish that its decision was clearly erroneous in view of the reliable, probative and substantial evidence on the whole record.

The evidence clearly indicates that a scanner is a vital part of today's medical diagnosis and that a hospital emergency room cannot function with full modern efficiency without it. The Commission's decision prejudiced substantial rights of the appellant and it is therefore reversed.

Paul J. Falsey
*United States District Judge*

# Ostomy: Personal Acceptance and Interpersonal Relations

PHILIP PRESSEL, E.T., B.S.M.E., M.S.M.E.
AND MARION PRESSEL, A.B., M.S.

Society defines many taboo subjects. As of late, the prohibitions in many areas have been relaxed and the attendant social stigma removed. Mental breakdowns, drug usage, alcoholism and mastectomy have become acceptable topics. But some of the proscriptions still remain. The excretory functions of the body are not suitable for discussion. This aggravates an already difficult situation with regard to acceptance.

## Personal Acceptance

The painfulness of sudden stigmatization can come not only from confusions about identity but from knowing too well what he has become.[3] The new ostomate has the task of accepting himself in a way which is totally contrary to the values of everyone in his culture.[5] [9] The ostomate usually feels that

> whatever others profess, they do not really 'accept' him and are not ready to make contact with him on 'equal grounds.' Further, the standards he has incorporated from the wider society equip him to be intimately alive to what others see as his failing, inevitably causing him . . . to agree that he does indeed fall short of what he really ought to be. Shame becomes a central possibility, arising from the individual's perception of one of his own attributes as being a defiling thing to possess, and one he can readily see himself as not possessing..[3] (p. 7)

An altered body is a cause of anger, grief, shame, and many other negative feelings.[5] [9] Disfigurement is not merely a question of appearance. For the ostomate, the structural change he undergoes is a reality which affects his perception of himself.[2]

In some cases it is possible for him to make an attempt to correct what he sees as the objective basis of his failing. Hence many ostomates have an obsession with regard to cleanliness and odor. Some colostomates who irrigate in an attempt to control evacuation, carry it to an extreme.[6]

The individual can also "attempt to correct his condition indirectly by devoting much private effort to the mastery of areas of activity ordinarily felt to be closed on incidental and physical grounds to one with his short coming."[3] (p. 10) The list of activities and occupations undertaken by ostomates is truly mind-boggling.

Often those with a particular stigma sponsor a publication voicing shared feelings, consolidating and stabilizing for the reader his sense of realness of "his" group and his attachment to it.[3]

## Interpersonal Relations

Our view of ourselves is also formed by the attitudes others have towards us.[2] The way we see ourselves determines to a very large degree our interactions with others, the type of image we display and the way people treat us.[7]

One of the first steps in personal acceptance is the finding of "sympathetic others."

> The first set of sympathetic others is of course those who share his stigma. Knowing from their own experience what it is like to have this particular stigma, some of them can provide the individual with instruction in the tricks of the trade and with a circle of lament to which he can withdraw for moral support and for the comfort of feeling at home, at ease, accepted as a person who is really like any other normal person.[3] (p. 20)

Easily 90 percent of the articles in the *Ostomy Quarterly* dealing with the emotional and physical adjustment to an ostomy mention either the great assistance rendered by a United Ostomy Association

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(UOA) visitor or bemoan the lack of one. The resources of a local ostomy chapter and the materials of the UOA can prove to be especially helpful. The ostomate is freed from earlier fears by the assurance that he need not face the future alone.[2]

The second set from whom the stigmatized person can hope for support are the "wise." These are normal people who are "intimately privy to the secret life of the stigmatized individual and sympathetic with it."[3] (p. 28) "Wiseness" may come from working in an establishment which caters either to the wants or needs of those with the stigma.[3] In this case, there exists a specialist, an Enterostomal Therapist* (ET), who is trained in the physical and psychological rehabilitation of the ostomy patient. There are approximately twelve E.T.s in Connecticut, roughly one for each UOA chapter. Unfortunately most hospitals do not have an E.T. or a nurse specializing in stoma or ostomy care. That means that many ostomy patients go without receiving the specialized care that they should get. Not enough physicians and surgeons know of the existence of E.T.s and even those that do often are reluctant to call one in if there is none in the hospital.

Another wise person is an individual who is "related" to the stigmatized person. "Ostomates depend most heavily on being accepted—stoma and all—by those nearest and dearest to them."[2] (p. 26) It is especially important for him to know that he is accepted by his loved ones.[4] In general, the tendency to treat the affected individual and his close connections as one provides a reason why such relations tend either to be avoided or terminated, if existing.[3] People who have known the ostomate prior to surgery may find difficulty in treating him with tact or maintaining the relationship on the same level as before since they have become attached to the way he once was.[3] Many people just don't know what to say.

The problem of sexual adjustment is very complex. Issues of sex and sexuality are of utmost importance to the ostomate—both male and female. Key to any sexual function is the need to feel socially acceptable, desirable, and appealing to the opposite sex.[8] Sometimes the fear of failure or of repelling the partner can contribute to the inability to perform.[1] Many males become concerned about their ability to perform sexually due to the proximity of the genitalia of the surgery.[4] They may worry that the surgery has severed nerves that affect the ability to achieve an erection. The response of the ostomate's partner is an integral part of the adjustment process. Rejection occurs to everyone but for the ostomate, it reinforces feelings of inacceptability.

Emotional support as well as physical care is an integral part of an ostomate's rehabilitation. Physicians are urged to utilize the E.T.'s skills in both of these fields in the team effort required for an ostomate's full return to a normal life.

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*An E.T. is an RN who receives a six week intensive "hands-on" care of ostomy patients training course at one of eleven medical schools in the U.S.

# The President's Page

## Letter to a Physician As Yet Unmade

Someday perhaps after graduating from medical school you will be approached by a middle-aged physician with a doleful expression. His sad demeanor will indicate concern, and, he may initiate a discussion with you relative to the oppressive nature of governmental intrusion upon the practice of medicine and the significant impact that it will make on your career. He may lament that during his lifetime the influence of physicians has waned and how the reduction in his stature has brought about a loss for him of one of the most rewarding aspects of the doctor-patient relationship. You will hear him complain about extensive review processes with the resultant parameters and cookbook medicine that have taken the joy out of his practicing medicine. He will tell you that the expanded role of the hospitals and the courts, in matters he feels are purely medical, will adversely affect your ability to practice your profession because of an abridgement of your freedoms. He will also note with sorrow that the influences of consumerism have reduced the role of the physician to that of a technician rather than that of a Renaissance man.

If you are a bright and sensitive soul, I am sure that this conversation will weigh heavily upon you. You will, of course, recognize that most of his concerns have a basis in verifiable fact. However, I would be remiss if I did not suggest the possibility that a somewhat similar conversation might have taken place between Aeschalapius and Hygeia had they ever met.

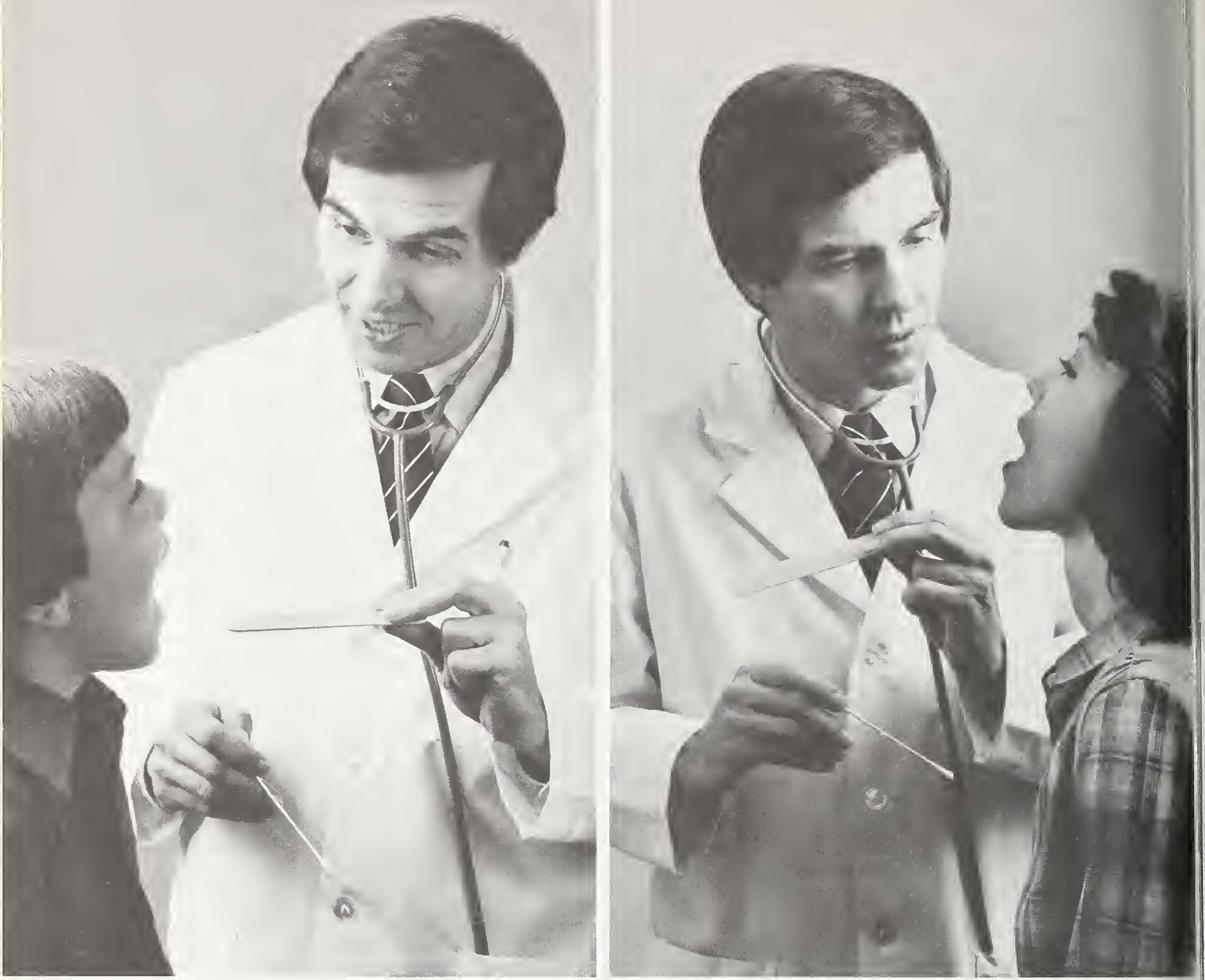
I may be a pessimist about the present but I am an unreserved optimist about the future, so I ask you not to despair. Your training will help prepare you for coping with those ever-changing external pressures, and your education will anticipate the changes taking place within the profession so that you will be better able to face them.

Even if governmental and public pressures continue to increase, your ability to cope with their effects will also increase.

As you go through life, new adventures will challenge you. You will be exposed to new joys and new sorrows with patients you encounter, and will soon find that yours is a profession whose horizons know no bounds and wherein the expansion of knowledge is unlimited. Revolutionary developments in technology are yet to come and you will achieve successes that have still to be dreamed. Hopefully you will extend life as well as improve its quality and in so doing will pass on to your children a tradition of service which they can respect and admire. Then one day when perchance you are in a reflective mood you will come to realize that your greatest accomplishment was not the financial position you achieved but rather the joy you've given to those people you served.

By that time, I expect that you too will have reached middle age and will realize that despite its problems your profession is still alive and well, that it slowly progresses because of loving care from you and your colleagues and that despite what Aeschalapius and Hygeia probably said to each other, it will continue to thrive and improve with each new generation of physicians.

Edward A. Kamens, M.D.
*President*



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# Reflections from the Dean's Office

## Simpler and Quieter

ROBERT U. MASSEY, M.D.

Last month I mentioned Osler's three guiding principles: life in day-tight compartments, the golden rule, and *aequinimitas.*

In a recent essay on Lady Osler there is a description of the Oslers' preparations for their move from Baltimore to Oxford. The last months had been hectic, and, three days before the sailing, Osler departed with his handbag with plans to meet his wife at the pier, leaving her to manage all the last minute tasks of packing and moving a household. She wrote in a letter: "Willie's motto may well be Aequinimitas because he always flies when things like this are going on."[1]

There is an old verb which has achieved a new place in psychologists' talk: *to cope,* and the ability to cope is regarded as a *critical success factor,* which, incidently, is a management phrase, also relatively new.

According to the Oxford dictionary, *cope* in its older usages had to do with fighting and was derived from the Latin *colaphus,* which in turn came from the Greek *kolaphos,* a blow with the fist. *Coup* in *coup d'etat* and *coup de grace* comes from the same source. By the seventeenth century *cope* had come to mean encountering dangers or difficulties with the implication of a successful outcome.

Although from its etymology *coping* suggests a confrontation with fists flying, one way to cope is to step aside and another is not to be there in the first place. Medical students must learn to cope with matters they have never encountered before: an arcane language, mountains of new information, human dissection, and a growing sense of awesome responsiblities. All of this is often accompanied by worries about mounting indebtedness with impossible interest rates, inflation, a neglected family, and a disintegrating automobile. Sometimes when you listen to a student in academic difficulty describing his sea of troubles you wonder how he made it this far.

It used to be easier. As medical students most of us never got into this fix in the first place. Medical school was mostly for those whose familes could afford it, and costs were not as high. Students rarely married so there were no spouse and children worries. Parents sometimes became ill and even died, but, since the family usually had reserves, that was seldom a financial tragedy. Living arrangements were simpler, often in a dormitory or a fraternity house, sometimes at home, but rarely requiring much managing. Few students had automobiles; street cars or bicycles served quite as well and there were no maintenance costs. There were worries about academic work, of course, and those problems could sometimes be terrifying. Tuberculosis or depression took its one or two from each class every year, but, as often as not, determined a new career direction.

Some students still manage to avoid most of the problems; they are lucky or they plan things better. But academic life in professional schools is harder than it was in the first half of this century; at least it is harder for students and faculty to follow an ideal academic life. For academic administrators the rule, as Barzun wrote, is *simplification.*[2] It should be written in big letters all over the place.

*Aequinimitas* is indeed a requirement. The alternative is panic. Because of the transformation, during the past 30 years, of the medical school into the academic medical center with all of the responsibilities for clinical services, community health, and research, and with simplicity denied by photocopying machines, computers, and a maddening bureaucracy, the only quiet place of learning is in the recesses of the library stacks.

When medical schools could be managed by a fulltime secretary and a parttime dean, and classes were smaller and students and senior faculty were together in the labs and at lunch, there was more time for education. Undoubtedly today's student has invented new ways to cope, but I suspect the number of casualties, major and minor, is higher, and higher than either we or the victims know.

*Aequinimitas,* always hard to attain, may elude our students when there are no quiet places and peaceful times in which to nourish it. Perhaps medical centers should try to become more like schools again; on reflection, that probably would not work because it is no good trying to solve new problems by reverting to old ways not designed for them. The answer, I suspect, is still in the two principles: *aequinimitas* and *simplification.* When resources are diminishing, the latter is a sound principle, and that may be the advantage of hard times!

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ROBERT U. MASSEY, M.D., Professor and Dean, School of Medicine, University of Connecticut Health Center, Farmington.

### REFERENCES

1. Harrell GT: Lady Osler, Bull. of the Hist. of Med. 53:81-99, 1979.
2. Barzun J: *The American University,* Harper & Row, New York, 1968, p. 132

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# The Laetrile Question

### JOSEPH M. HEALEY, J.D.

The recent death of Chad Green is a poignant reminder of the bitter dispute within our society about the appropriate use of Laetrile. The extent to which a cancer patient may choose to supplement or replace chemotherapy with Laetrile treatment is a source of major controversy and disagreement. In a decision during its 1978-79 term,[1] the United States Supreme Court considered a request by several terminally ill patients and their spouses seeking to prevent federal interference with their access to Laetrile. While the decision of the Court did not resolve conclusively the Laetrile controversy, it nonetheless provides an important framework for future discussion.

Section 505 of the Federal Food, Drug and Cosmetic Act[2] prohibits the distribution through interstate commerce of any new drug unless the Secretary of Health, Education and Welfare approves the use of the drug after reviewing substantial evidence of the drug's safety and effectiveness. Under the statute, a new drug is defined as a drug which is not generally recognized by experts as safe and effective under the conditions prescribed. Exemptions from the premarketing approval procedures are limited by the statute to the investigative use of the drug and to two grandfather clauses protecting drugs in use before the enactment of the legislation. Terminally ill cancer patients and their spouses filed suit in Federal District Court to enjoin Government interference through the Act with the sale and shipment of Laetrile in interstate commerce.

This case has a complicated litigation history. The United States District Court for the Western District of Oklahoma initially found that Laetrile in proper dosages was nontoxic and effective, and ordered the Government to allow purchases of the drug by the plaintiffs. On appeal, the Tenth Circuit Court of Appeals remanded the case back to the District Court with the instruction that it be determined by the Food and Drug Administration whether Laetrile was a new drug under the Federal Food, Drug and Cosmetic Act. After a series of hearings, the Commissioner of the Food and Drug Administration found that Laetrile was a new drug under the Act, concluded that there were no adequate, well-controlled studies of its safety or effectiveness, and found that it failed to qualify for an exemption under either of the grandfather clauses.[3] The District Court, reviewing the Commissioner's decision, sustained each of his findings except the denial of an exemption under one of the grandfather clauses. The Court went further to hold that the Constitutional right of privacy protected the right of cancer patients to use a nontoxic substance, Laetrile, in connection with their personal health. On appeal, the Court of Appeals addressed neither the statutory nor the Constitutional aspects of the District Court's decision, but focused on the status of terminally ill cancer patients. Since these patients by definition are proximate to death, the safety and effectiveness requirements of the Act were found to have no reasonable application for them. As a result, the Court of Appeals permitted the intravenous injection of Laetrile to terminally ill patients under a doctor's supervision. The case was then appealed to the United States Supreme Court.

Mr. Justice Marxhall delivered the opinion for a unanimous Court. He pointed out that a review of the legislative history and the administrative interpretation of the Act failed to disclose any exemption from the requirements of the Act for drugs used by the terminally ill. He rejected the finding of the Court of Appeals that the safety and effectiveness requirements have no reasonable application to terminally ill patients. He cited the example of an individual suffering from a potentially fatal disease who rejects conventional therapy for a drug with no demonstrable curative properties. The consequences of such a rejection could be irreversible. For this reason, Marshall argues, the Food and Drug Administration even before the 1962 amendments to the Act considered effectiveness when reviewing the safety of drugs used to treat terminal illness. The judgment of the Court of Appeals was reversed and the case remanded for further proceedings.

The Supreme Court refused to address either the constitutional or the statutory issues raised by the District Court because the Court of Appeals failed to address either issue. In remanding the case, the Supreme Court invited further proceedings on these issues. We can expect to hear more in the future about them. The Rutherford case represents a temporary resolution not a permanent solution. The Laetrile question will remain with us for some time.

### REFERENCES

1. *U.S. v. Rutherford*, 47 LW 4724 (1979)
2. 21 U.S.C. 321
3. 42 Federal Regulations 39768 (1977)

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JOSEPH M. HEALEY, J.D., Assistant Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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# EDITORIALS

## To Tell or Not To Tell the Cancer Patient

I believe the answer for the cancer patient should be a qualified yes, Yes, because it's his life and he has a right to know. Qualified, because not every patient is able to handle it. People vary greatly in their capacity to deal with adversity. While there are a few who should not be told, there are none who should be told routinely and indiscriminately—in fulfillment of a standard protocol requirement. The physician owes to each and every one a respect for his individuality and a concern to do no harm.

The controversy over this question is diminishing. Our society today tends to "let it all hang out." We have become much more open. For most people this works out well. However, there are many for whom cancer still does bring visions of disfigurement, decay and early death. It is, therefore, vitally important that we consider the setting, the timing, the manner, and the content of our telling before we proceed with it. We owe it to the patient to take the time and trouble to judge his ability to deal with the facts of life. While ultimately we are each responsible for ourselves, our ability to carry this load varies greatly. We should keep in mind that some patients really don't want to be told; can't deal with being told; and shouldn't be told. For those who are to be told, the patient should be prepared for the telling, the timing should be carefully chosen, the telling should be gentle and an element of hope should always be preserved.

We should let the patient tell us by word, manner or deed whether and when he is ready to be told. Whether intentionally or not, the patient will communicate his reluctance or his readiness to know. We need to be wary of any unwitting tendency in ourselves to ascribe to the patients our own attitudes toward health, disease and death. By conscious effort, the physician can sharpen his awareness skills and learn how better to read the patient's signals. Among those which call for special attention are a lifelong history of marked dependecy with evidence of a lack of inner resources, a history of decompensation and personality disorganization in response to an earlier illness interpreted by the patient as life-threatening, a history of deaths from cancer among family members, a verbalized threat of suicide "if I ever had cancer." None of these is an absolute contraindication to telling. Each is, however, a caution signal; and suggests the need to weigh carefully the pros and cons of telling this particular patient.

In all cases, when you do tell the patient, be ready to support him. Neither hurry nor force him to acknowledge what you have told him. Give him a chance to digest the information and work it through. He may need to deny it for a time, to let it sink in, to assimilate it. Certainly he is entitled to this. Our attention to the patient's welfare must encompass concern for his feelings as well as treatment for his cancer.

Bernard V. Strauss, M.D.

*Chairman, Department of Psychiatry,*
*Danbury Hospital; Lecturer in Psychiatry*
*Yale University School of Medicine*

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# COMMITTEE SERVICE QUESTIONNAIRE
## Connecticut State Medical Society

Early in 1980 the Councilors from the eight constituent county medical associations assume the responsibility of selecting members of the Society to participate in the various activities of the Society listed below. In making these selections it is of importance to choose physicians who are not only willing and able to serve but also who are known to have an interest in the work of the group to which they may be assigned. In order to enable this office to furnish the Councilors with a compilation of those who desire to be considered for committee service, all members are asked to indicate by number in order of preference (not more than three) opposite your choice in the questionnaire below and return same to the:

Executive Director's Office
160 St. Ronan Street
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Your cooperation will be appreciated.

**Medical Education**

- ☐ Committee on Continuing Medical Education
- ☐ Committee on Program of the Scientific Assembly

**Medical Economics**

- ☐ Committee on Insurance
- ☐ Committee on Professional Liability
- ☐ Committee on Peer Review Systems
- ☐ Committee on Third Party Payments

**Professional Relations**

- ☐ Judicial Committee

**Public Affairs and Communications**

- ☐ Editorial Committee of "Connecticut Medicine"
- ☐ Committee on Legislation
- ☐ Committee on Public Relations

**Scientific and Socio-Environmental Medicine**

- ☐ Committee on Emergency Medical Services
- ☐ Cancer Coordinating Committee
- ☐ Committee on Drug Abuse Educational Programs
- ☐ Committee on Maternal Morbidity and Mortality
- ☐ Committee on Medical Aspects of Sports
- ☐ Committee on Mental Health
- ☐ Committee on Organ and Tissue Transfers
- ☐ Committee to Study Perinatal Morbidity and Mortality
- ☐ Committee on Public Health
- ☐ Committee on Continuing Medical Care and Rehabilitation
- ☐ Committee on Statewide Medical Planning

**Representatives and Advisors**

- ☐ Committee on Allied Medical Services
- ☐ Committee on Hospitals
- ☐ Committee on Cooperation with the Medical Schools of Connecticut
- ☐ Liaison Committee with Connecticut Pharmaceutical Association
- ☐ Liaison Committee with State Department of Income Maintenance
- ☐ Representatives to Connecticut Advisory School Health Council
- ☐ Delegates to Connecticut Health Association, Inc.
- ☐ Delegates to Connecticut Nutrition Council
- ☐ Representatives to Connecticut Advisory Committee on Foods and Drugs
- ☐ Delegates to Council of New England State Medical Societies

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Robert J. Brunell
*Assistant Executive Director*
*Scientific Activities*

Richard J. Fiorentino
*Coordinator*
*Special Services*

## COUNCIL MEETING

Thursday, October 18, 1979

### Attendance

Present were: Drs. Kamens, James Canzonetti, Backhus, Ragland, Jr., Freedman, Hess, Van Syckle, Cramer, McGarry, Rubinow, Anderson, Magram, Parrella, F. Barrett, Zlotsky, Jameson, Beck, J. Barrett, Shenker, Eslami, Tierney, Bobruff and Sonnen.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Fiorentino, Mr. Tomat (FCMA) and Dr. S. Bongard, UConn. School of Medicine.

### Approval of Minutes

It was VOTED to approve the minutes of the meeting of August 8, 1979, as published and distributed.

### Reports from Physicians Serving on State and Federal Agencies

Statewide PSRC Council—Dr. Andrew J. Canzonetti reported that the Council was finalizing plans for a conference on Nov. 26 on the problems of long term care facilities—particularly in Fairfield County. According to the PSRO Council, nursing home rates in Connecticut have been inadequate and are considerably lower than those in New York, which is the cause of many residents of New York occupying extended care facility beds in Connecticut and creating a shortage in Connecticut.

HSA—Dr. Orvan W. Hess mentioned that HSA #2 was considering several proposals to provide for more bed capacity for nursing homes and extended care facilities and reported that the state health plan may be completed by December.

Medical Examining Board—Dr. Jerome K. Freedman reported that the Board desired reasonably timed hearings on complaints brought before the body but was being frustrated in those efforts by various delay tactics. Dr. Edward A. Kamens mentioned that Dr. Isadore H. Friedberg had testified recently at a legislative hearing on the subject of the Examining Board and had done a most commendable job in representing the Society's concerns to the legislators.

Connecticut Commission on Hospitals and Health Care—Dr. Merrill B. Rubinow reported on activities of the Commission and commented that it was his opinion that vital equipment has been denied to various institutions because of recent Commission actions.

### Committee on Emergency Medical Services

It was VOTED to authorize the Committee on Emergency Medical Services to undertake the formulation of a plan, together with the Department of Health, for the handling of radiation accidents.

### AMA Meeting on the Voluntary Effort

It was VOTED to accept with commendations the report of Dr. Isadore H. Friedberg on the meeting held in Denver, Colorado on the Voluntary Effort.

### Membership of AMA Councils

It was VOTED to nominate Dr. Orvan W. Hess for a position on the AMA Council on Medical Education and Dr. Jerome K. Freedman for membership on the AMA Council on Continuing Physician Education.

### Report of the President

AMA Negotiations Seminar—President Kamens reported that the recent conference on negotiations was most helpful and that the Society should consider a similar program of its own at some future date.

### Metropolitan Life Insurance Company Second Opinion Program

Dr. Kamens reported on the ad hoc committee meeting held earlier in the week with Dr. Robert Henderson of Metropolitan Life.

After discussion of Metropolitan's offer of a second opinion program it was VOTED to reaffirm the official CSMS position on the subject. The position is as follows:

> "Recognizing that the advisability of surgery (or other specific therapy) can be a matter of opinion, the House of Delegates of the Connecti-

cut State Medical Society (1) reaffirms the right of a patient or a physician to seek consultation freely with any consultant of his/her choice; (2) opposes the concept of mandatory consultation when required by a third party payor; (3) supports the concept that when consultation is required by a third party payor, the consultation should be at no cost to the patient; (4) opposes the concept of closed panels of consultants; (5) supports the concept that if consultation is required by a third party payor, the patient should be allowed to choose a physician of his/her choice."

### Blue Cross/Blue Shield Medicare Proposal

The President reported on his attendance at a recent briefing on the new Medicare proposal, and a general discussion on the subject followed his remarks. It was VOTED to hold a special meeting of the Council on Wednesday, October 31 (1:30 P.M.) for the purpose of hearing the views of Blue Cross/Blue Shield and Connecticut General on the new proposal.

### Committee on Professional Liability

Dr. Kamens and Dr. Gioacchino S. Parrella (Chairman) reported on the recent meeting of the Committee on Professional Liability. Dr. Parella mentioned to the Council that his committee had formed subcommittees in order to perform an exhaustive study on all of the professional liability options available to the Society. The subcommittees are looking into offshore insurance companies, joint underwriting associations, a CSMS captive and other alternatives to the present program.

### Resignations of Dr. James Root

Dr. Kamens reported on the receipt of a letter which Dr. James Root asked to be relieved of his CSMS committee assignments. It was VOTED to accept Dr. Root's resignations with regret along with commendation and thanks for the many responsibilities which he carried out so well for the Society. It was VOTED further to make Dr. Root a honorary member of CSMS if he should move from Connecticut, and to recognize him by resolution at the Semi-Annual Meeting of the House of Delegates.

### Committee on Hospitals

It was VOTED to appoint Dr. Herbert Magram, Middletown, Chairman of the Committee on Hospitals, to succeed Dr. James Root, who resigned the position. It was further VOTED to appoint Dr. Isadore H. Friedberg, Newington, to replace Dr. Root on the Committee.

### Medicare Hearing in Hartford

Dr. Sidney Cramer reported on a recent hearing held in Hartford on the subject of the Medicare program.

### Report of Fiscal Subcommittee RE Budget for 1980

It was VOTED to approve of the budget as submitted to the Council which includes a recommendation that the dues be increased by $25, from the present $100 to $125, and to transmit same to the House of Delegates with a recommendation for approval by the House.

*Journal Survey:* In an effort to control costs of the publication of *Connecticut Medicine,* it was VOTED to approve the recommendation of the Fiscal Subcommittee that a survey of CSMS members be made to determine whether or not they wish to continue to receive the Journal.

### CSMS Public Relations

Dr. Benjamin Shenker, Middletown, discussed the subject of public relations and offered recommendations to the Council for consideration of the Committee on Public Relations. It was VOTED to refer Dr. Shenker's suggestions to the committee as follows:

1) Consider instituting a monthly newspaper article entitled, "Your Doctors' Viewpoint."
2) Consider frequently publicizing a Connecticut physician, his or her accomplishments, civic contributions, etc.
3) Consider collecting and interpreting complete up-to-date information on social, political, and economic factors which relate to medicine.

Dr. Shenker's complete list of suggestions and recommendations will be submitted to the Committee on Public Relations.

### Report of the AMA Ad Hoc Committee on the Principles of Medical Ethics

Dr. Guy W. Van Syckle discussed the background and recent history of proposed changes in the AMA's Principles of Medical Ethics. After discussion, it was agreed to postpone consideration of the issue until the special meeting on October 31, due to the loss of a quorum at 5:45 P.M.

Council Chairman Andrew J. Canzonetti introduced Mr. Richard Fiorentino to the Council members as the new CSMS Coordinator of Special Services.

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on October 18, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

## COUNCIL MEETING

Wednesday, October 31, 1979

### Attendance

Present were: Drs. Kamens, James, Canzonetti, Mendillo, Ragland, Jr., Sadowski, Freedman, Hess, Van Syckle, Fabro, Cramer, Parrella, F. Barrett, Zlotsky, Jameson, Beck, Abbot, J. Barrett, Eslami and Tierney.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sweeney, Mr. Fiorentino and Mr. Tomat (FCMA).

### Approval of Minutes

It was VOTED to approve the minutes of the meeting of October 18, 1979, as published and distributed.

### Blue Cross/Blue Shield Medicare Proposal

Representatives of Blue Cross/Blue Shield (Mr. Joseph Duplinsky, President; Bruce Thayer, M.D., Sr. Vice President, Medical and Professional Affairs; Mr. Jack Caroweak, Executive Vice President; Mr. Frank Delaney, Vice President of Claims and Ron Klar, M.D., Consulting Analyst) addressed the Council on their new Medicare proposal. Following the presentations and a question and answer period, representatives of Connecticut General (Mr. Lindsay Hanna, Manager of Governmental Operations, and Thomas Feeney, M.D., Medical Consultant-Medicare) gave their views on the new program and also answered questions.

### Federal Trade Commission

Attorney Linda Randell reported on the recent FTC decision to uphold the Judge Barnes opinion with certain modifications. The Commission agreed with Judge Barnes that it had jurdisdiction in the case and that the medical societies and associations involved had conspired to restrain trade. Ms. Randell opined that the decision as written could signal the death knell of medical society review of fees, a service performed in response to patient requests. She reported that, in short, the FTC found that the CSMS had violated the law but did not name the Society in any cease and desist order. After discussion, it was VOTED unanimously to reaffirm the CSMS House of Delegates action of 5/2/79 "to carry the appeal as far as needed to either achieve a successful conclusion or exhaust all avenues of redress."

### Connecticut Academy of Family Practice

It was VOTED to accept as information the Academy guidelines for physicians remuneration for services provided to Medicaid recipients.

### COMPAC

It was VOTED to appoint Drs. Joseph Sadowski, Jerome Freedman, Frank Abbot, W. Raymond James and Norman Zlotsky to the Ad Hoc CSMS Organization Political Committee.

### 1979 State Medical Journal Advertising Bureau Conference

It was VOTED to accept as information the report from Dr. J. Alfred Fabro on his attendance at the subject meeting.

### Report of the AMA Ad Hoc Committee on the Principles of Medical Ethics

After discussion, it was VOTED to have Dr. Guy Van Syckle present a report and resolution at the Interim Meeting of the House of Delegates (November 15) on the issue of the Principles of Medical Ethics and, furthermore, that sufficient background information be mailed in advance to the members of the House of Delegates.

### Cumulative Minutes of Committee Meetings

It was VOTED to receive as information and transmit to the Journal Editor the minutes of committee meetings held as follows: Committee of the Medical Aspects of Sports, 8/9/79; Committee on Professional Liability, 9/11/79 and Committee on Allied Medical Services, 10/3/79.

**N.B.:** *The foregoing is a summary of the proceedings and actions of the Council on October 31, 1979. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

## PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical pofession in the State of Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan Street, New Haven, Connecticut 06511 (203-865-6822).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two consecutive issues of *Connecticut Medicine* as space permits.

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(If no name is listed, contact the Physician Placement Service for more details.)

Physician fully qualified professional with full training in Internal Medicine, Surgery, or Family Practice to fill a position in the Emergency Room. Experience: 2 years post graduate school, 4 years medical school, plus 2 residency. 40 hours per week, rotating shifts. Sunday through Saturday. $42,000 annual salary. Contact: Mrs. Catherine Bresnahan, Personnel Director, St. Mary's Hospital, 56 Franklin St., Waterbury, Ct. 06702. Telephone 574-6223. EOE.

Primary Care Physicians NCC-HMO in East Hartford seeking Bd.-cert. or Bd.-elig. internists. Exciting, innovative group practice setting, located near med. sch. in new facility. Positions available beginning Summer '80. Salary, fringes competitive. Send CV to Daniel Burns, M.D., Medical Director, NCC-HMO, 99 Ash Street, East Hartford, CT 06108. 568-8500. EEO.

Part-time position available at Wesleyan University Health Center for physician specializing in Internal Medicine, Family Practice or Pediatrics. Contact Helen Davis, M.D., FAAP, University Physician, Wesleyan University, Middletown, Ct. 06457, (203) 347-9411, ext. 217 for further details.

### FAMILY PRACTICE

Family Practice residency graduates wanted July '80 to join a 3 doctor group with unique make-up. Two recent residency graduates and previous Director, UConn residency. Hospital-sponsored group practice will grow to 6 doctors plus Nurse Practitioners and Health Educator. Serves area of family doctor shortage, yet only 10 miles from New Haven and one hour from New York City. Competitive salary and fringes. POMR. Family practice involves active in-patient, medical and pediatrics, no OB. Tertiary level consultation at two Connecticut Medical Schools. Contact Dr. John Donnelly 203-929-7331.

### PEDIATRICS

Third Pediatrician sought for active group doing pediatric and adolescent medicine in eastern Ct. near beach activities and rural living. Grossing $200,000+ and still growing. Send CV to CSMS Ped.-KMP.

### PHYSICIANS WISHING TO LOCATE IN CONNECTICUT

### ALLERGY

Allergy-Internal Medicine: July '80. Age 28. FLEX. Cert.-IM; Elig.-Allergy. MD: India. Int. and res.: Jamaica Hosp., NY. Fellowship: St. Univ. of NY-Buffalo. Willing to do part-time IM. Wishes grp., assoc., or institutional practice in large or med. community. Desai G. Krishnarao, M.D., 770 West Ferry, #11B, Buffalo, NY 14222.

### ANESTHESIA

July '80. Age 29. Conn. license pending. AB-elig. MD: India. Int.: Kings County Hosp., NY. Res. and fellowship: Albert Einstein. Wishes grp. or assoc. practice in large or med. community in Ct. Mukesh N. Gatha, M.D., 1935 E. Chestar Rd., Apt. #22C, Bronx, NY 10461.

Anesthesia-General Practice: Jan. '80. Age 48. Conn. license. AB-elig. Presently in practice. 16 yrs. experience, trained in Ct., and residing in the state, available for coverage, long locum tenens, or full time. Call 227-1484.

### FAMILY MEDICINE

Aug. or Sept. '80. Age 28. Nat'l. bds., elig. MD: Univ. of PA. Int. and res.: Thomas Jefferson Hosp., PA. No Ob. Prefers location near Guilford, but will consider other areas. Rural or sm. town. Prefers to practice with or near husband (Fred Markham, M.D.) also Family phy. Grp., assoc., institutional or industrial practice desired. Anne L. duBreuil, M.D., 950 Walnut St., Apt. #310, Barringer Hall, Philadelphia, PA 19107.

July '80. Age 29. Nat'l. bds., elig.-7/80. MD: Jefferson. Int. and res.: Hunterdon Med. Ctr. Solo, grp., assoc., or institutional type practice desired in Ct. Eric N. Kruger, M.D., Hunter Hills, G-4, Flemington, NJ 08822.

Aug. or Sept. '80. Age 28. Nat'l. bds., elig. MD: Dartmouth. Int., res. and fellowship: Thomas Jefferson Hosp. No Ob. Prefers location near Guilford, but will consider other areas. Rural or sm. town. Prefers to practice with or near wife (Anne L. duBreuil, M.D.) also Family phy. Grp. assoc. institutional or industrial practice desired. Fred W. Markham, M.D., 950 Walnut St., Apt. #310, Barringer Hall, Philadelphia, PA 19107.

Available now. Age 43. Part of Nat'l. bds., Presently in practice. MD: Univ. of TX., Galveston. Int.: Hermann Hosp., TX. Primary interest in Student Health or a salaried position, will consider grp., assoc., or industrial position. Thomas W. Lister, M.D., Rt 3, Box 417CD, Cameron, TX 76520.

### INTERNAL MEDICINE

Rheumatology: July '80 or earlier with notice. Nat'l. bds., elig. MD: Cornell. Int. and res.: Boston City Hosp. Fellowship: Hospital of Univ. of PA. Prefers grp. practice in a hospital affil. with med. sch. with good housestaff. Prefers to do all Rheu., but will be happy with general med. in part. Contact CSMS/IM-Rheu.-S.P.B.

Available May-Sept. '80. Chest Diseases. Conn. license. MD: St. Louis Univ. Int.: Yale New Haven Hosp. Res.: US Public Health Service. Fellowship: Marine Hosp., Staten Island and Holley State Hosp., Fla. Presently in practice. Looking for a locum tenens. Herman S. Cutler, M.D., 3460 S. Ocean Blvd., Palm Beach, FL 33480.

Cardiology: July '80. Age 29. Nat'l. bds., cert. MD: New York Med. Coll. Int. and res.: North Shore Univ. Hosp. Fellowship: Beth Israel Med. Ct., NJ. Wishes solo, grp. or assoc. practice in large or med. community. George Demidowich, M.D., 501 Stuyvesant Ave., Irvington, NJ 07111.

Cardiology: July '80. Age 35. FLEX. AB-cert. MD: Berlin. Int. and res.: Mt. Sinai Hosp., CT. Fellowship: SUNY-Buffalo. Wishes solo, grp. or assoc. practice in CT. Martin P. Echt, M.D., 34 Tomcyn Dr., Amherst, NY 14221.

Pulmonary: July '80. Age 30. Nat'l. bds., cert., elig.-Pulmonary. MD: SUNY. Int., res. and fellowship: Albert Einstein-Bronx Municipal Hosp. Ctr. Fully trained in all aspects of IM and Pulmonary. Solo, grp. or assoc. practice in CT. Michael S. Falkowitz, M.D., 245-20 Grand Central Parkway, Bellerose, NY 11426.

Rheumatology: July '80. Age 27. Nat'l. bds. MD: Jefferson. Int., res. and fellowship: George Washington Univ. Hosp. Also res.: US

## INTERNAL MEDICINE - CONTINUED

V.A. Hosp., Washington. Also fellowship: St. Vincent's Hosp., MA. Solo, grp. or assoc. practice desired in Ct. Contact CSMS/IM-Rheu.-R.D.G.

July '80. Age 30. Conn. license. Nat'l. bds., elig.-6/80. MD: Univ. of Bologna. Int. and res. Mt. Sinai, Hartford. Solo, grp. or assoc. practice desired in CT. Jay Kaplan, M.D., 140 Kane St., Apt. D2, West Hartford, CT 06119.

Pulmonary Diseases: July '80. Age 28. Nat'l. bds., cert. MD: New York Med. Coll. Int. and res.: St. Vincent's Hosp., NY. Fellowship: Tufts-New England Med. Ctr. Interested in either grp. practice or assoc.; a hospital based instit. practice is less desirable. Primary interest Pul., willing to practice gen. IM as well. Robert J. Keltner, Jr., M.D., 106 Appleton St., Boston, MA 02116.

Cardiology: July '80. Age 35. AB-cert. MD: India. Int. and res.: Mt. Vernon Hosp. Fellowship: Maine Med. Ctr. and St. Francis Hosp., CT. Solo, grp. or assoc. practice desired in CT. Contact CSMS/IMCard.-KMM.

Gastroenterology: July '80. Age 28. AB-cert.-IM; elig.-GI. MD: NY Med. Coll. Int. and res.: Metropolitan Hosp. Ctr. Fellowship: Emory. Univ. trained, all endoscopic procedures, including EROP, polypectomy. Grp. assoc. or academic practice in large or med. community. Ira E. Mayer, M.D., 3193D Buford Hwy., NE, Atlanta, GA 30329.

Cardiology: July '80. Age 32. Nat'l. bds., cert. MD: Univ. of Kerala. Int.: Leeds Univ. Hosp., England. Res.: St. Francis Hosp., NJ. Fellowship: William Beaumont Hosp., MI. Will consider all types of practice in CT. Kochunni Mohan, M.D., 4016 W. 13 Mile Rd., #15, Royal Oak, MI 48072.

Available now. Age 27. Passed VQE. Presently in practice. MD: MRCS, LRCP, United Kingdom. Int.: London-Suffolk. Res.: Birmingham. Qualified at St. Bartholomew's Hosp., London. Prefers to practice IM in hospitals. Alan Peiris, M.D., 19 Beverley Court, Wellesley Rd., London W4 4LQ.

Available now. Age 31. Nat'l. bds., cert. Presently in practice. MD: Tufts. Int. and res.: Baystate Med. Ctr., MA. Wishes grp. or assoc. practice in med. community. Robert P. Rosenthal, M.D., 66 Bickford Hill Road, Gardner, MA 01440.

Endocrinology: Oct. '79. Age 34. Nat'l. bds., cert. MD: Cornell. Int.: Greenwich Hosp., Ct. Res.: Roosevelt Hosp., NY. Fellowship: Syracuse-SUNY. Wishes to practice half endocrinology and IM within a grp. in a med. community in Ct. Nestor B. Tomycz, M.D., 1531 S. 25th Ave., Fargo, ND 58102.

## OBSTETRICS AND GYNECOLOGY

July '80. Age 29. Nat'l. bds., elig. MD: Columbia P & S. Int.: Overlook Hosp. Res.: Columbia Presbyterian. Wishes grp. practice in CT. Robert L. Daniels, M.D., 60 Haven Ave., 9-E, New York, NY 10032.

July '80. Age 32. Nat'l. bds. MD: Bologna Univ. Int. and res.: Jewish Hosp. and Med. Ctr. of Brooklyn. Experience in Laparoscopy, Colposcopy. Solo, grp. or assoc. practice desired. Contact CSMS/Ob-Gyn.-RJL.

Available now. Age 34. Nat'l. bds., elig. Presently in practice. MD: NJ Coll. of Med. Res.: UConn. Wishes grp. practice in med. community. Richard J. Malafy, M.D., Box 31, Frankstown Rd., Hollidaysburg, PA 16648.

July '80. Age 28. Nat'l. bds., elig. MD: NY Med. Coll. Res.: Columbia-Presbyterian Med. Ctr. Wishes grp. practice in Ct. Robert A. Stern, M.D., 7 Balint Dr., #128, Yonkers, NY 10710.

July '80. Age 32. FLEX. AB-elig. MD: Cairo. Int.: Cairo Univ. Hosp's. Res's.: United Kingdom and Med. Coll. of Ohio. Wishes grp. or assoc. practice in large community. Ali Azaki, 6631 W. Bancroft St., Toledo, OH 43615.

## OPHTHALMOLOGY

July '80. Age 31. Applied for Ct. license. Nat'l. bds., elig. MD: Einstein. Int.: Beth Israel, NY. Res.: Manhattan Eye & Ear. Gen. ophth. with special interest in I.O.L., and med. retina. Solo or assoc. practice desired in Ct. Contact CSMS/Ophth.-ANL.

Jan. '80. Age 36. FLEX. Nat'l. bds., elig. MD: Charles Univ. of Prague, Czech. Int.: Provident Hosp., Baltimore. Res.: Hahnemann. Fellowship: Johns Hopkins. Will consider all types of practice except industrial. Contact CSMS/Ophth.-DSM.

## ORTHOPEDIC SURGERY

June '80. Age 31. Nat'l. bds., elig. MD: Creighton. Int. and res.: Stonybrook, also res.: Hamot Med. Ctr., PA. Wishes grp. or assoc. practice in CT. Nicholas Cappello, M.D., 663 Young Rd., Erie, PA 16509.

July '80. Age 40. Nat'l. bds., elig. FLEX. MD: Univ. of Sri Lanka. Int.: Coney Island Hosp. Grp. or assoc. practice desired in med. community in Ct. Contact CSMS/Orth.-CD.

July '80. Age 34. Nat'l. bds., elig. MD and int.: Temple. Res.: Hosp. of Joint Diseases, NY. Wishes solo, grp. or assoc. practice in large or med. community in Ct. Ellio N. Lang, M.D., 356 Central Ave., Scarsdale, NY 10583.

## OTOLARYNGOLOGY

July '80. Age 29. FLEX. AB-elig. MD: Guadalajara. Int.: SUNY-Stonybrook (Surg.) Res.: Columbia Presbyterian. Solo, grp. or assoc. practice desired in large or med. community in CT. Jeffrey Adelglass, M.D., 12E 86th St., #229, New York, NY 10028.

## PEDIATRICS

Ped.-Family Med.: Available now. Age 39. Conn. license. Nat'l. bds., elig. MD: Univ. of Pittsburgh. Int. and res.: Indiana Univ. Med. Ctr. Interested in Family Practice and Child Development. Solo, grp. or institutional practice in CT. Richard M. Stevko, M.D., P.O. Box 194, Roxbury, CT 06783.

## SURGERY

Thoracic and Cardio.: Aug. '80. Age 35. Nat'l. bds., AB-cert.-surg.; elig.-thoracic and card. MD: George Washington Univ., DC. Int. and res.: Washington Hosp. Ctr., DC. Fellowship: Cleveland Clinic Foundation. Wishes grp., assoc. or institutional practice in a large community in CT. Louis T. Kanda, M.D., 12000 Edgewater Dr., Lakewood, OH 44107.

Available immediately. Age 30. Nat'l. bds., AB-Part I. MD: Downstate. Int. and res.: Kings County Hosp.-Downstate. Wishes solo practice in sm. community. Contact CSMS/G. Surg.-KMP.

July '80. Age 35. AB-elig. MD: India. Int.: Maimonides Med. Ctr., NY. Res.: Good Samaritan Hosp., OH. Assoc. or institutional practice desired in med. community. Hardas Rathod, M.D., 4985 Hawaiian Terr., Cincinnati, OH 45223.

July '80. Age 33. Nat'l. bds., cert. Presently in practice. MD, int. and res.: George Washington Univ. Wishes solo or grp. practice in Ct. Thomas F. Street, M.D., 529 Bluegrass Court, Orange Park, FL 32073.

## UROLOGY

Aug. '80. Age 31. Nat'l. bds., elig. MD: Loyola-Stritch. Int.: Rochester Gen. Hosp. Res.: Univ. of Rochester Hospitals. Grp. or assoc. practice in large or med. community. Contact CSMS/Urol.-WAM.

Aug. '80. Age 30. Nat'l. bds., elig. MD: Einstein. Int., res. and fellowship: Montefiore Hosp. Solo, grp. assoc. or (institutional part-time) practice desired in large or med. community. Daniel P. Wiener, M.D., 3236 Steuben Ave., Bronx, NY 10467.

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